ARNOLD & PORTER LLP

Developing an Effective 510(k) Strategy in a Resource-Constrained Environment

Q1 Productions Webinar

Mahnu Davar
Philip Desjardins
Jul. 24, 2014

Today's Agenda

- Regulatory framework for 510(k)s
- Planning for an effective and efficient filing
- Traditional 510(k) route
- The *de novo* option
- Post-marketing considerations
- Q&A

FDA Regulation of Medical Devices

- Under US law, a medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
  - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  - intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

FDA Regulation of Medical Devices (cont'd)

- Medical devices are classified in three classes (I, II, III), Class III being highest risk
  - Class I devices are generally exempt from premarket review
  - Class II devices typically require FDA Premarket Notification under section 510(k) of the US Food, Drug, and Cosmetic Act (establishing substantial equivalence to predicate)
  - Where no suitable predicate device is available, devices are automatically designated as Class III (Premarket Approval)
- *De novo* process allows for risk based classification of "novel" low risk devices

FDA Approval or Clearance Pathways

- 510(k) – Substantially equivalent to a legally marketed predicate
- *De novo* – risk-based classification of a device without a valid predicate (reasonable assurance of safety and effectiveness)
- PMA – valid scientific evidence demonstrating reasonable assurance of safety and effectiveness; generally the default for a new technology

Which Pathway is the Right Fit for My Technology?

- What is the market opportunity?
- What is the clinical landscape like? Is it well studied?
- What claims/intended uses do I want?
- Do my claims/intended uses match my technology?
- Has FDA previously reviewed a similar product?
- Is this a new technology for FDA? Or is there a clear predicate/pathway?
- Should we meet with FDA before filing anything?
- What are our production and post-marketing requirements?

Pre-Submission Meetings with FDA

Top 5 tips to getting value out of a FDA Meeting

1. Know your device!
2. Do your homework
3. Come with a plan
4. Keep an open mind and listen to what FDA tells you
5. Document your interactions with the Agency

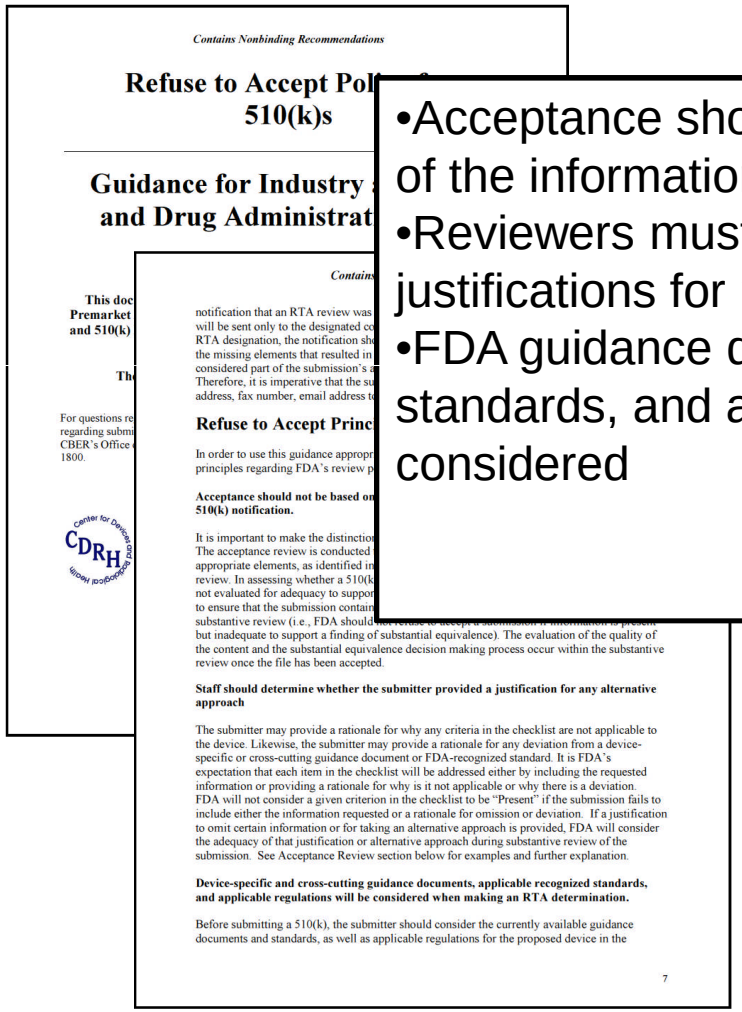
510(k) Standards

- Applicant demonstrates Substantial Equivalence ("SE") to legally marketed device
  - Intended Use
  - Technological Characteristics
  - Safe and effective under conditions promoted
- If Intended Use and/or Technological Characteristics are not the same, may lead to Not Substantially Equivalent ("NSE") determination
- Notification by FDA of acceptance of 510(k) application results in a "clearance" to lawfully market (not an "approval")

510(k) Refuse to Accept (RTA) Principles

- Acceptance review only starts once the User Fee has been paid and a validated eCopy has been received
- Should FDA fail to complete the acceptance review within the review period (i.e., within 15 calendar days of receipt:
  - Submitter will be notified in writing that acceptance review was not completed and the submission is under substantive review
  - Substantive review can still include RTA review
  - FDA staff are to provide the submitter a copy of the completed checklist
- FDA staff are to provide the submitter a copy of the completed checklist

RTA: Basic Principles



Contains Nonbinding Recommendations

Refuse to Accept Poli… 510(k)s

Guidance for Industry … and Drug Administrat…

Contains…

notification that an RTA review was … will be sent only to the designated co… RTA designation, the notification sh… the missing elements that resulted in … considered part of the submission's … Therefore, it is imperative that the su… address, fax number, email address to…

Refuse to Accept Princ…

In order to use this guidance appropr… principles regarding FDA's review p…

Acceptance should not be based on … 510(k) notification.

It is important to make the distinction… The acceptance review is conducted … appropriate elements, as identified in … review. In assessing whether a 510(k)… not evaluated for adequacy to suppor… to ensure that the submission contain… substantive review (i.e., FDA should … but inadequate to support a finding of substantial equivalence). The evaluation of the quality of the content and the substantial equivalence decision making process occur within the substantive review once the file has been accepted.

Staff should determine whether the submitter provided a justification for any alternative approach

The submitter may provide a rationale for why any criteria in the checklist are not applicable to the device. Likewise, the submitter may provide a rationale for any deviation from a device-specific or cross-cutting guidance document or FDA-recognized standard. It is FDA's expectation that each item in the checklist will be addressed either by including the requested information or providing a rationale for why is it not applicable or why there is a deviation. FDA will not consider a given criterion in the checklist to be "Present" if the submission fails to include either the information requested or a rationale for omission or deviation. If a justification to omit certain information or for taking an alternative approach is provided, FDA will consider the adequacy of that justification or alternative approach during substantive review of the submission. See Acceptance Review section below for examples and further explanation.

Device-specific and cross-cutting guidance documents, applicable recognized standards, and applicable regulations will be considered when making an RTA determination.

Before submitting a 510(k), the submitter should consider the currently available guidance documents and standards, as well as applicable regulations for the proposed device in the

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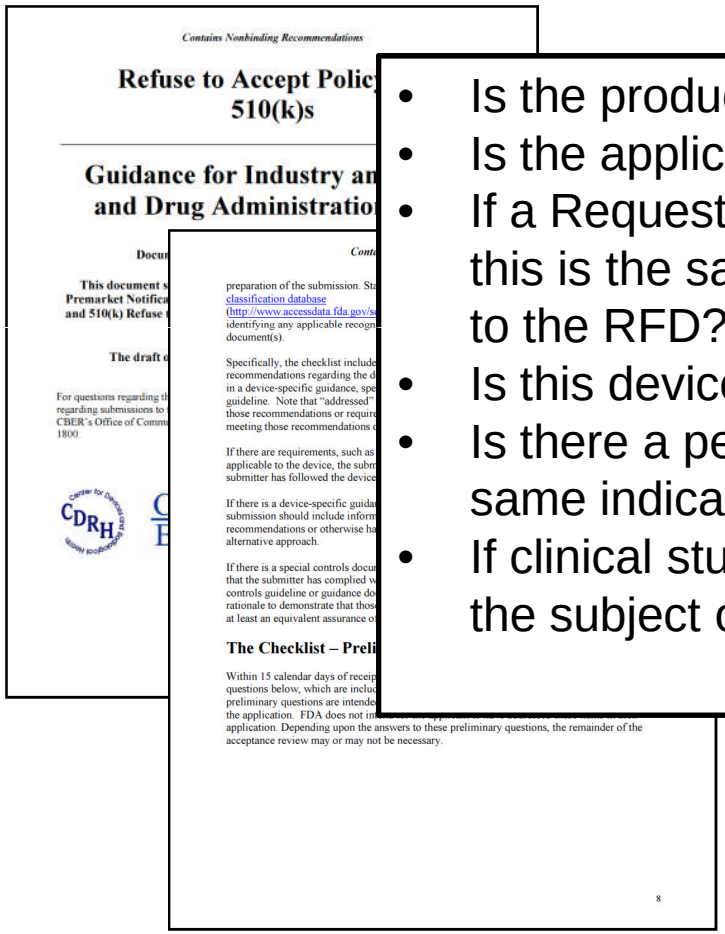
- Acceptance should not be based on a substantive review of the information
- Reviewers must determine whether submitter provided justifications for reasonable alternative approaches
- FDA guidance documents, applicable recognized standards, and applicable regulations must have been considered

RTA: Preliminary Questions



- Is the product a device or combination product?
- Is the application with the appropriate Center?
- If a Request for Designation (RFD) was submitted confirm this is the same product and indications as were subject to the RFD?
- Is this device type eligible for 510(k) submission?
- Is there a pending PMA for the same device with the same indications?
- If clinical studies have been submitted, is the submitted the subject of the Application Integrity Policy?

RTA: MDUFA III Goals

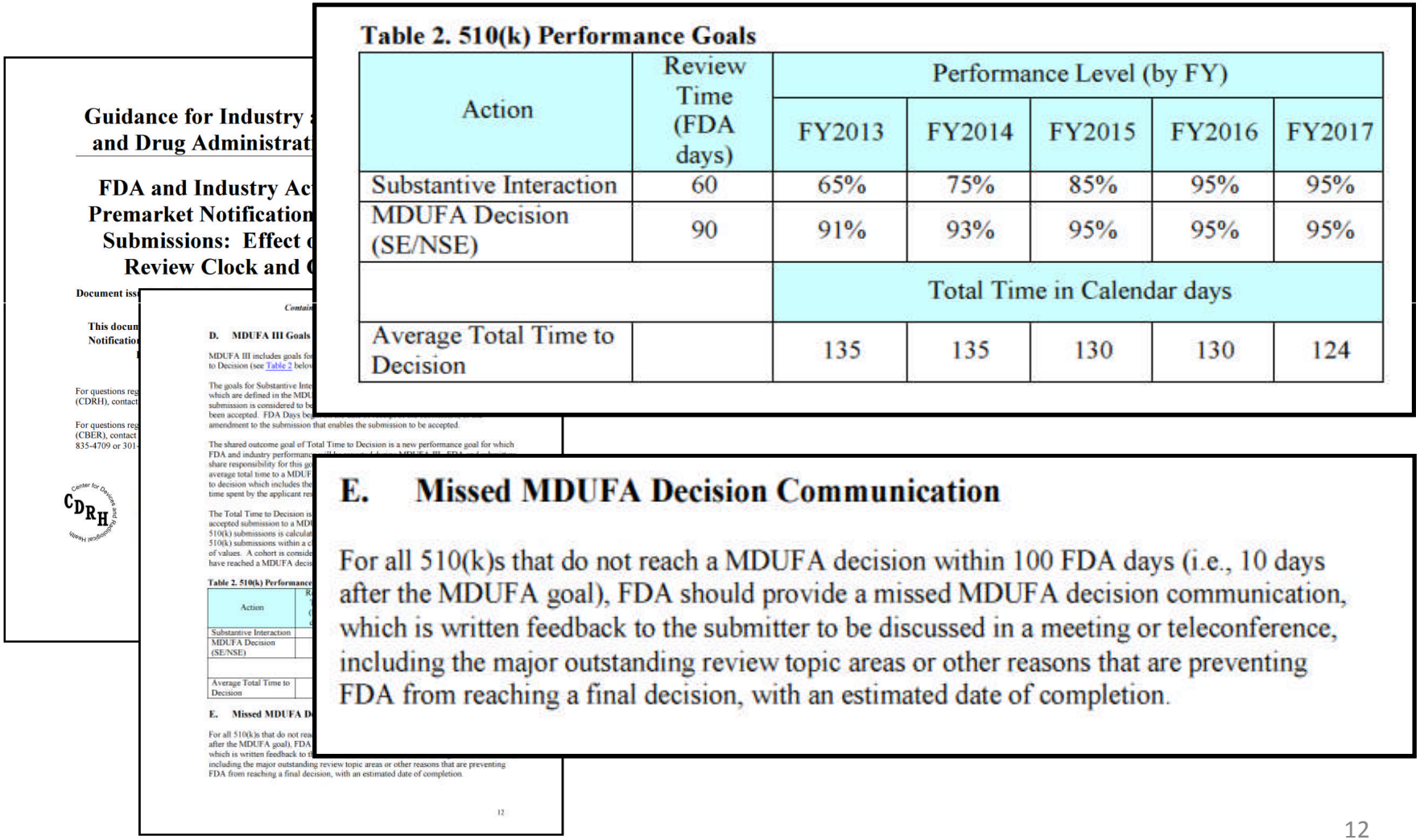


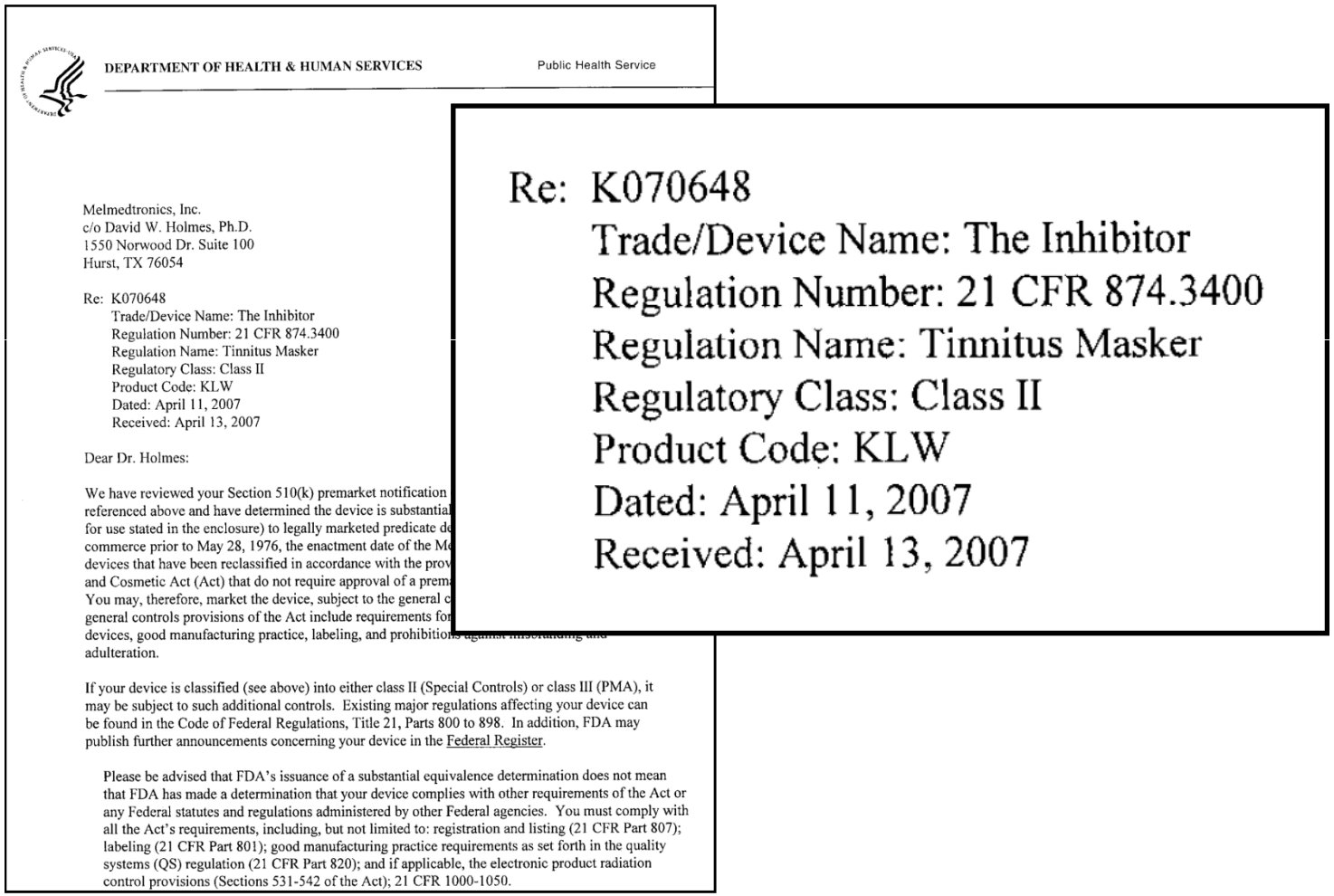
Table 2. 510(k) Performance Goals

Action	Review Time (FDA days)	Performance Level (by FY)				
		FY2013	FY2014	FY2015	FY2016	FY2017
Substantive Interaction	60	65%	75%	85%	95%	95%
MDUFA Decision (SE/NSE)	90	91%	93%	95%	95%	95%
		Total Time in Calendar days				
Average Total Time to Decision		135	135	130	130	124

E. Missed MDUFA Decision Communication

For all 510(k)s that do not reach a MDUFA decision within 100 FDA days (i.e., 10 days after the MDUFA goal), FDA should provide a missed MDUFA decision communication, which is written feedback to the submitter to be discussed in a meeting or teleconference, including the major outstanding review topic areas or other reasons that are preventing FDA from reaching a final decision, with an estimated date of completion.

Example of 510(k) Clearance: Tinnitus Masker



DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Melmedtronics, Inc.
c/o David W. Holmes, Ph.D.
1550 Norwood Dr. Suite 100
Hurst, TX 76054

Re: K070648
Trade/Device Name: The Inhibitor
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: April 11, 2007
Received: April 13, 2007

Dear Dr. Holmes:

We have reviewed your Section 510(k) premarket notification
referenced above and have determined the device is substantial
for use stated in the enclosure) to legally marketed predicate de
commerce prior to May 28, 1976, the enactment date of the Me
devices that have been reclassified in accordance with the prov
and Cosmetic Act (Act) that do not require approval of a prema
You may, therefore, market the device, subject to the general c
general controls provisions of the Act include requirements for
devices, good manufacturing practice, labeling, and prohibition
adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
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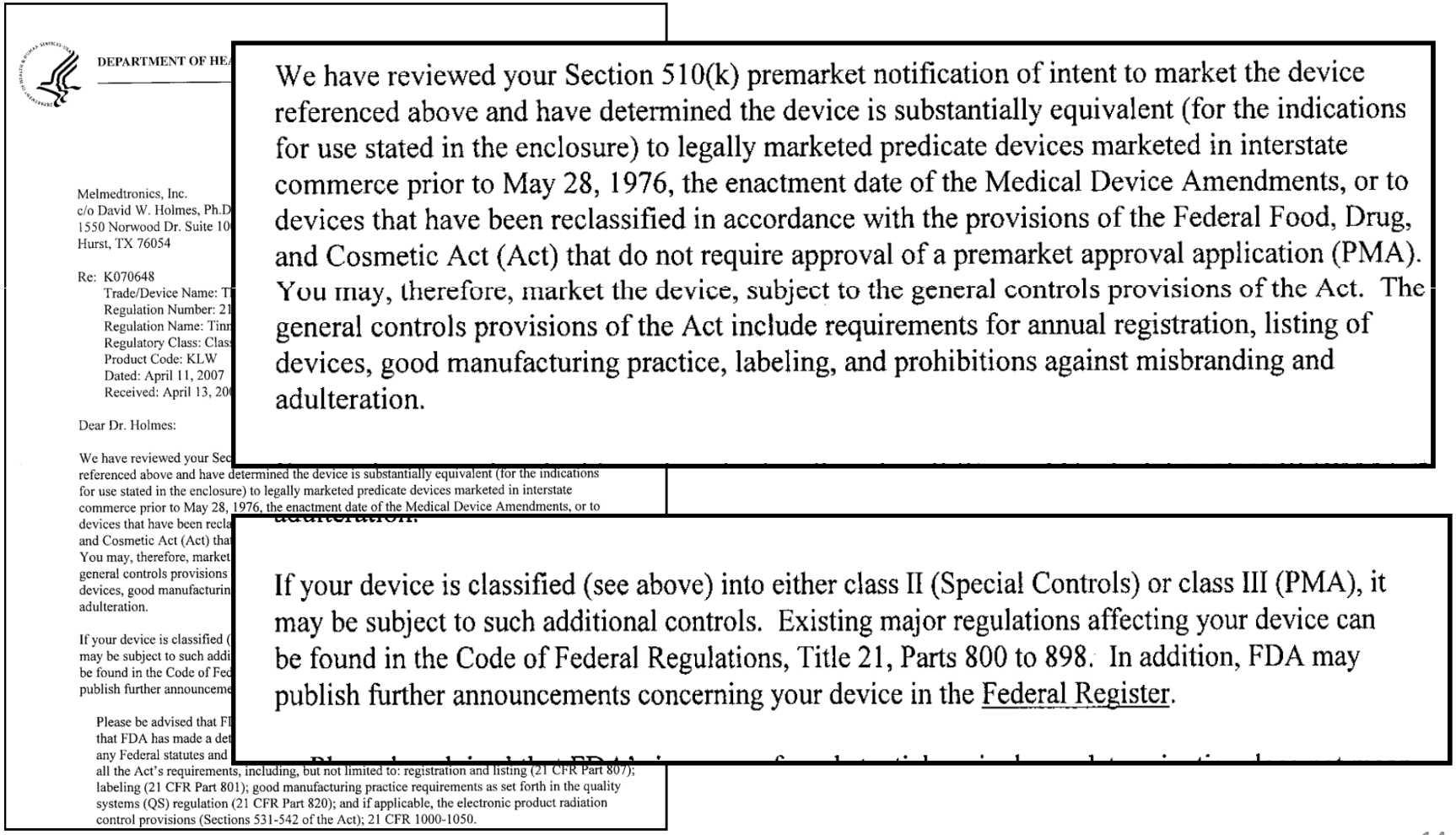
Example of 510(k) Clearance (cont'd)



DEPARTMENT OF HE

Melmedtronics, Inc.
c/o David W. Holmes, Ph.D
1550 Norwood Dr. Suite 10
Hurst, TX 76054

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Regulatory Class: Class
Product Code: KLW
Dated: April 11, 2007
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Dear Dr. Holmes:

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publish further announceme

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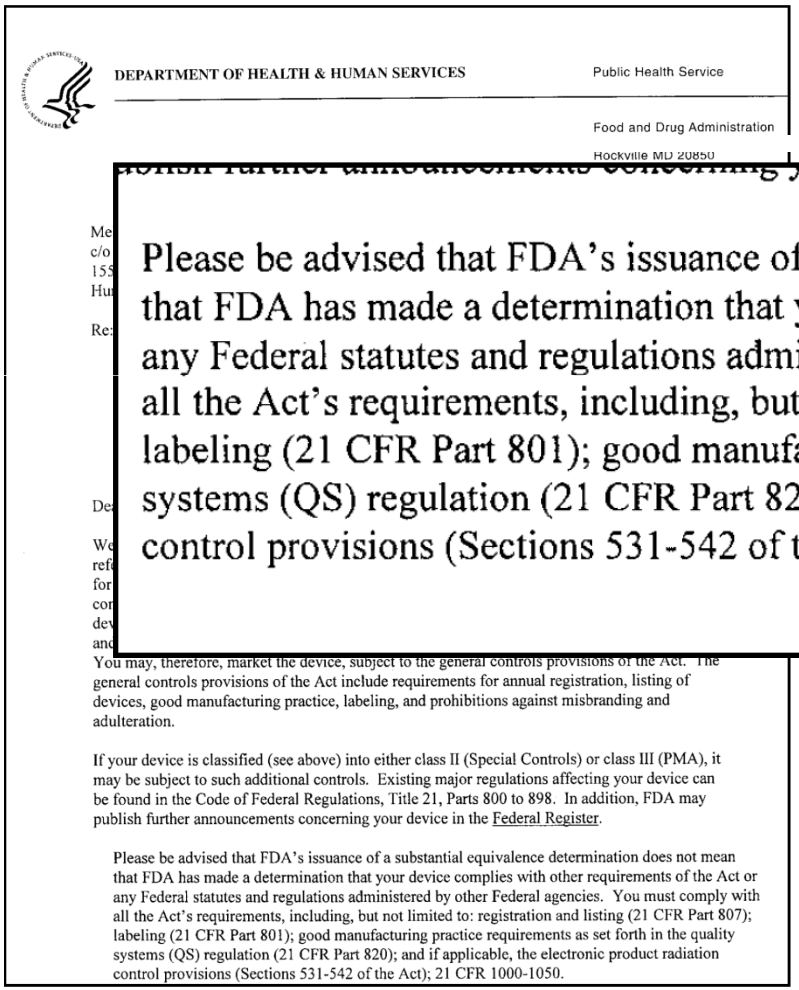
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Example of 510(k) Clearance (cont'd)



DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration

Hockville MD 20850

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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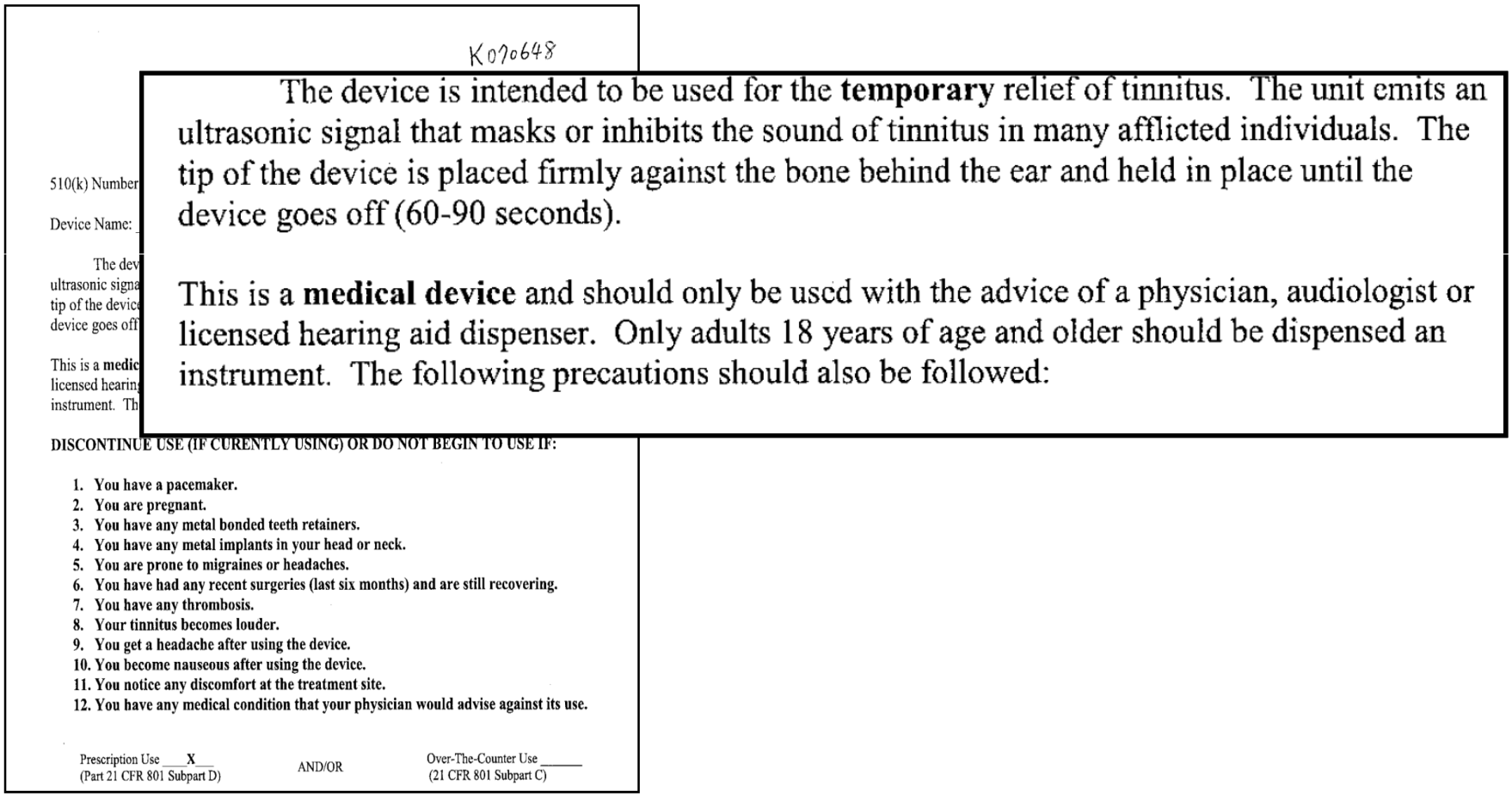
Example of 510(k) Clearance: Intended Use



K070648

510(k) Number

Device Name:

The dev
ultrasonic signa
tip of the device
device goes off

This is a **medic**
licensed hearing
instrument. Th

The device is intended to be used for the **temporary** relief of tinnitus. The unit emits an ultrasonic signal that masks or inhibits the sound of tinnitus in many afflicted individuals. The tip of the device is placed firmly against the bone behind the ear and held in place until the device goes off (60-90 seconds).

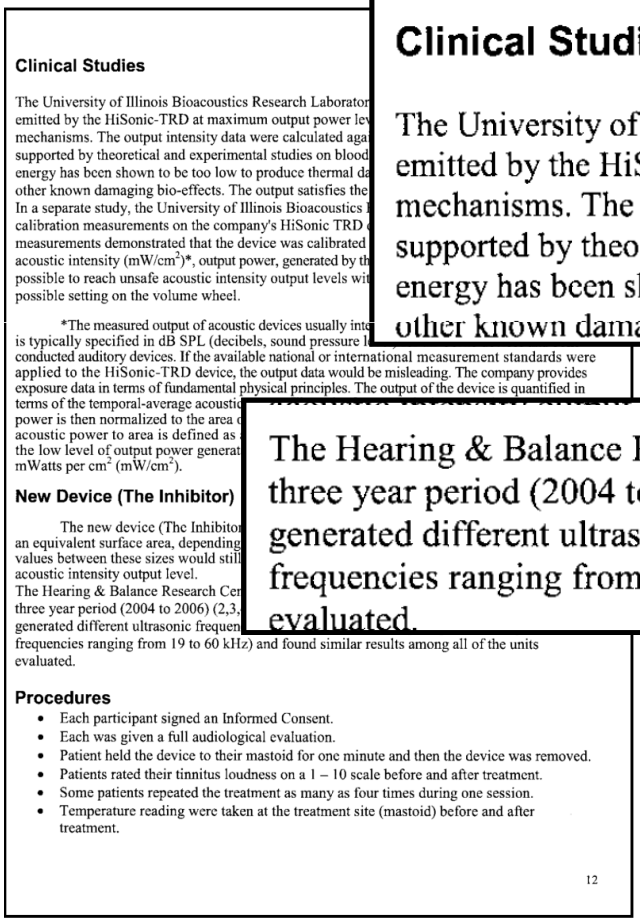
This is a **medical device** and should only be used with the advice of a physician, audiologist or licensed hearing aid dispenser. Only adults 18 years of age and older should be dispensed an instrument. The following precautions should also be followed:

DISCONTINUE USE (IF CURENTLY USING) OR DO NOT BEGIN TO USE IF:

1. **You have a pacemaker.**
2. **You are pregnant.**
3. **You have any metal bonded teeth retainers.**
4. **You have any metal implants in your head or neck.**
5. **You are prone to migraines or headaches.**
6. **You have had any recent surgeries (last six months) and are still recovering.**
7. **You have any thrombosis.**
8. **Your tinnitus becomes louder.**
9. **You get a headache after using the device.**
10. **You become nauseous after using the device.**
11. **You notice any discomfort at the treatment site.**
12. **You have any medical condition that your physician would advise against its use.**

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Example of 510(k) Clearance (cont'd)



Clinical Studies

The University of Illinois Bioacoustics Research Laborator
emitted by the HiSonic-TRD at maximum output power lev
mechanisms. The output intensity data were calculated aga
supported by theoretical and experimental studies on blood
energy has been shown to be too low to produce thermal da
other known damaging bio-effects. The output satisfies the
In a separate study, the University of Illinois Bioacoustics
calibration measurements on the company's HiSonic TRD
measurements demonstrated that the device was calibrated
acoustic intensity (mW/cm^2)*, output power, generated by th
possible to reach unsafe acoustic intensity output levels wit
possible setting on the volume wheel.

*The measured output of acoustic devices usually inte
is typically specified in dB SPL (decibels, sound pressure l
conducted auditory devices. If the available national or international measurement standards were
applied to the HiSonic-TRD device, the output data would be misleading. The company provides
exposure data in terms of fundamental physical principles. The output of the device is quantified in
terms of the temporal-average acoustic
power is then normalized to the area
acoustic power to area is defined as
the low level of output power generat
mWatts per cm^2 (mW/cm^2).

New Device (The Inhibitor)

The new device (The Inhibitor
an equivalent surface area, depending
values between these sizes would still
acoustic intensity output level.
The Hearing & Balance Research Cer
three year period (2004 to 2006) (2,3,
generated different ultrasonic frequen
frequencies ranging from 19 to 60 kHz) and found similar results among all of the units
evaluated.

Procedures

- Each participant signed an Informed Consent.
- Each was given a full audiological evaluation.
- Patient held the device to their mastoid for one minute and then the device was removed.
- Patients rated their tinnitus loudness on a 1 – 10 scale before and after treatment.
- Some patients repeated the treatment as many as four times during one session.
- Temperature reading were taken at the treatment site (mastoid) before and after treatment.

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Clinical Studies

The University of Illinois Bioacoustics Research Laboratory (9) measured the ultrasound energy emitted by the HiSonic-TRD at maximum output power levels against known injury mechanisms. The output intensity data were calculated against a standard thermal model supported by theoretical and experimental studies on blood and intact tissues. The ultrasound energy has been shown to be too low to produce thermal damage and too low to produce any other known damaging bio-effects. The output satisfies the safety limits of IEC 61689.

The Hearing & Balance Research Center in Hurst, Texas conducted several clinical trials over a three year period (2004 to 2006) (2,3,4,5,6,7,). They compared several ultrasonic devices that generated different ultrasonic frequencies (broadband noise, sweep frequencies, single frequencies ranging from 19 to 60 kHz) and found similar results among all of the units evaluated.

But What Are My Options If…

- My product is a medical device that I believe is:
  - Safe; and
  - Will be subjected to applicable manufacturing, quality, and labeling controls.
- But:
  - I can't find a predicate;
  - I don't have or can't produce clinical data to support a PMA; and
  - My management and shareholders don't want an NSE or automatic PMA classification.

De Novo Classification: History

- Pre-1997: regardless of risk, 510(k) or PMA
- The Food and Drug Administration Modernization Act (1997) added the *de novo process*
  - Required a 510(k) + NSE
- Food and Drug Administration Safety and Innovation Act (2012)
  - Novel (no valid predicate)
  - Low to moderate risk
  - No 510(k) or NSE required

De Novo Process

- There are two regulatory paths for *de novo* classification
  - Option 1: Any person who receives an NSE determination in response to a 510(k) submission may, within 30 days of receipt of the NSE determination, submit a *de novo* request for the FDA to make a risk-based evaluation for classification of the device into Class I or II.
  - Option 2: Any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may submit a *de novo* request for the FDA to make a risk-based classification of the device into Class I or II, without first submitting a 510(k) and receiving an NSE determination.

- Devices that are classified through the *de novo* process may be marketed and used as predicates for future 510(k) submissions.

De Novo Process: Choosing the Right Path

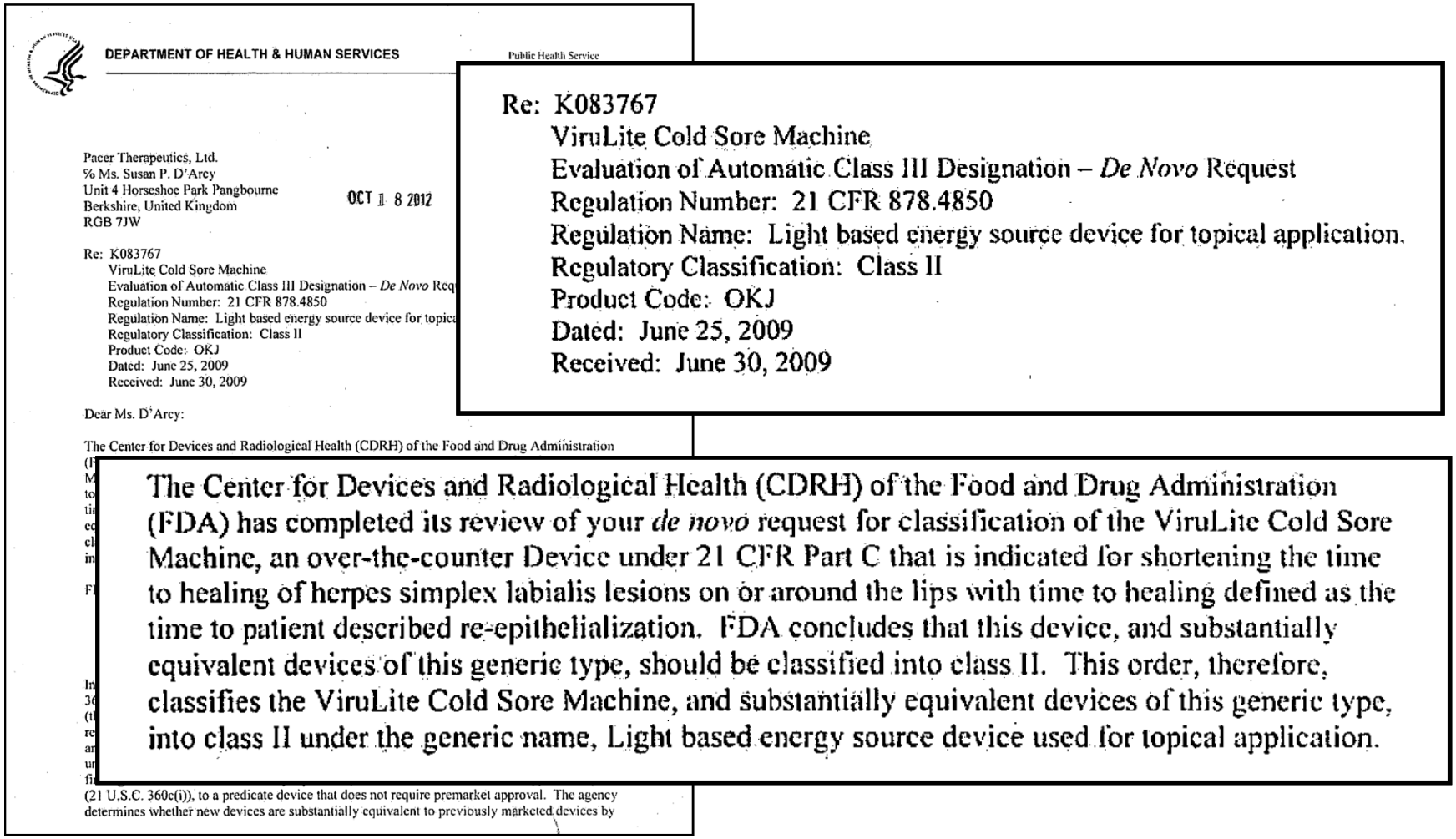
- 510(k) + *de novo* request
  - Could be a less burdensome path
  - Leverage the work of competitors
- Original *de novo* request
  - More Data
  - Guiding the way for competitors
  - Faster

An Efficient *De Novo* Process

Pre-*De Novo* Submission

- Provides early interaction w/ FDA
  - suitability of *de novo* process
  - data requirements necessary to support safety and effectiveness
- Intended to facilitate *de novo* petition review and identify potential road blocks
- [***Remember our 5 tips for meeting with FDA!]

Example of *De Novo* Clearance



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Pacer Therapeutics, Ltd.
% Ms. Susan P. D'Arcy
Unit 4 Horseshoe Park Pangbourne
Berkshire, United Kingdom
RGB 7JW

OCT 1 8 2012

Re: K083767
ViruLite Cold Sore Machine
Evaluation of Automatic Class III Designation – *De Novo* Req
Regulation Number: 21 CFR 878.4850
Regulation Name: Light based energy source device for topica
Regulatory Classification: Class II
Product Code: OKJ
Dated: June 25, 2009
Received: June 30, 2009

Dear Ms. D'Arcy:

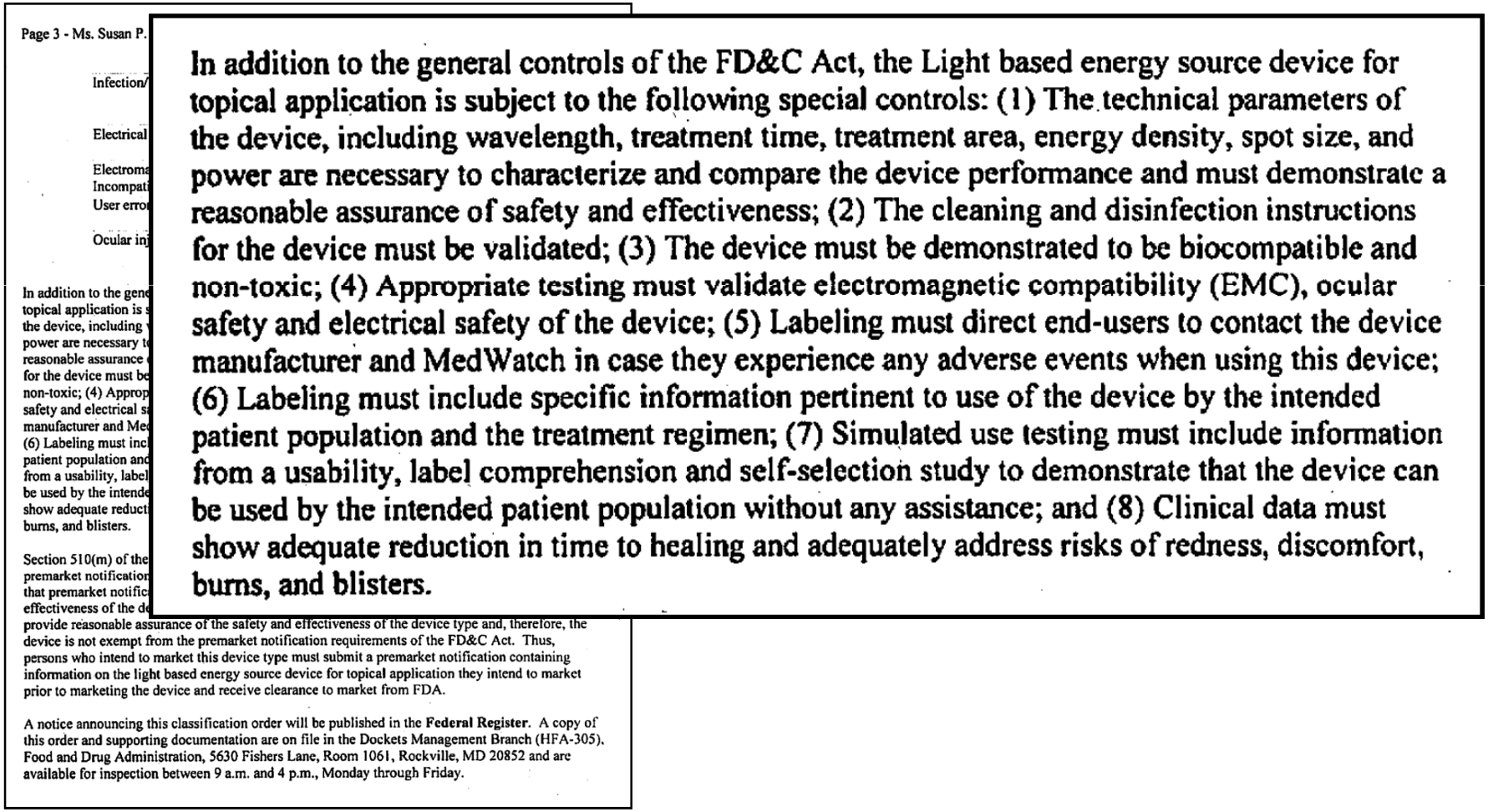
The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration

(21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by

Re: K083767
ViruLite Cold Sore Machine
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 878.4850
Regulation Name: Light based energy source device for topical application.
Regulatory Classification: Class II
Product Code: OKJ
Dated: June 25, 2009
Received: June 30, 2009

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the ViruLite Cold Sore Machine, an over-the-counter Device under 21 CFR Part C that is indicated for shortening the time to healing of herpes simplex labialis lesions on or around the lips with time to healing defined as the time to patient described re-epithelialization. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the ViruLite Cold Sore Machine, and substantially equivalent devices of this generic type, into class II under the generic name, Light based energy source device used for topical application.

Example of *De Novo* Clearance (cont'd)



Page 3 - Ms. Susan P.

Infection/

Electrical

Electroma
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User erro

Ocular inj

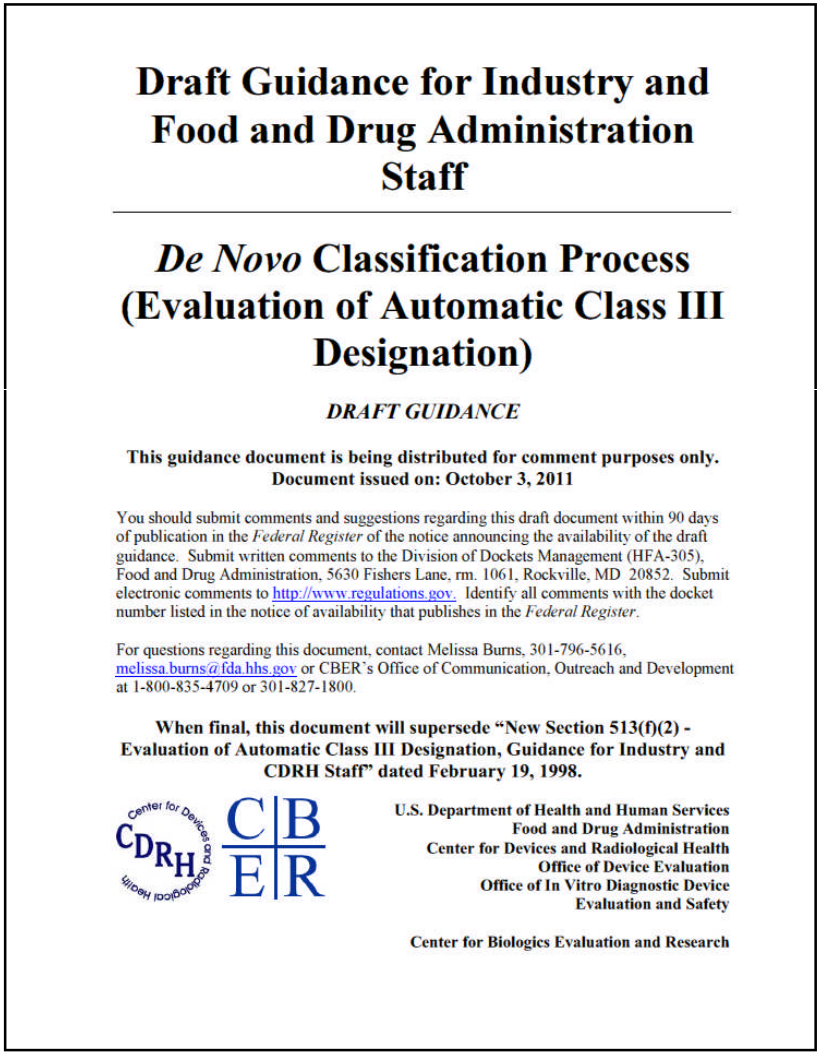
In addition to the gene
topical application is s
the device, including
power are necessary t
reasonable assurance
for the device must be
non-toxic; (4) Approp
safety and electrical s
manufacturer and Me
(6) Labeling must inc
patient population and
from a usability, label
be used by the intende
show adequate reduct
burns, and blisters.

Section 510(m) of the
premarket notificatio
that premarket notific
effectiveness of the de
provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the light based energy source device for topical application they intend to market prior to marketing the device and receive clearance to market from FDA.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

In addition to the general controls of the FD&C Act, the Light based energy source device for topical application is subject to the following special controls: (1) The technical parameters of the device, including wavelength, treatment time, treatment area, energy density, spot size, and power are necessary to characterize and compare the device performance and must demonstrate a reasonable assurance of safety and effectiveness; (2) The cleaning and disinfection instructions for the device must be validated; (3) The device must be demonstrated to be biocompatible and non-toxic; (4) Appropriate testing must validate electromagnetic compatibility (EMC), ocular safety and electrical safety of the device; (5) Labeling must direct end-users to contact the device manufacturer and MedWatch in case they experience any adverse events when using this device; (6) Labeling must include specific information pertinent to use of the device by the intended patient population and the treatment regimen; (7) Simulated use testing must include information from a usability, label comprehension and self-selection study to demonstrate that the device can be used by the intended patient population without any assistance; and (8) Clinical data must show adequate reduction in time to healing and adequately address risks of redness, discomfort, burns, and blisters.

De Novo Guidance – Outdated but Useful



Draft Guidance for Industry and Food and Drug Administration Staff

De Novo Classification Process (Evaluation of Automatic Class III Designation)

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: October 3, 2011

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

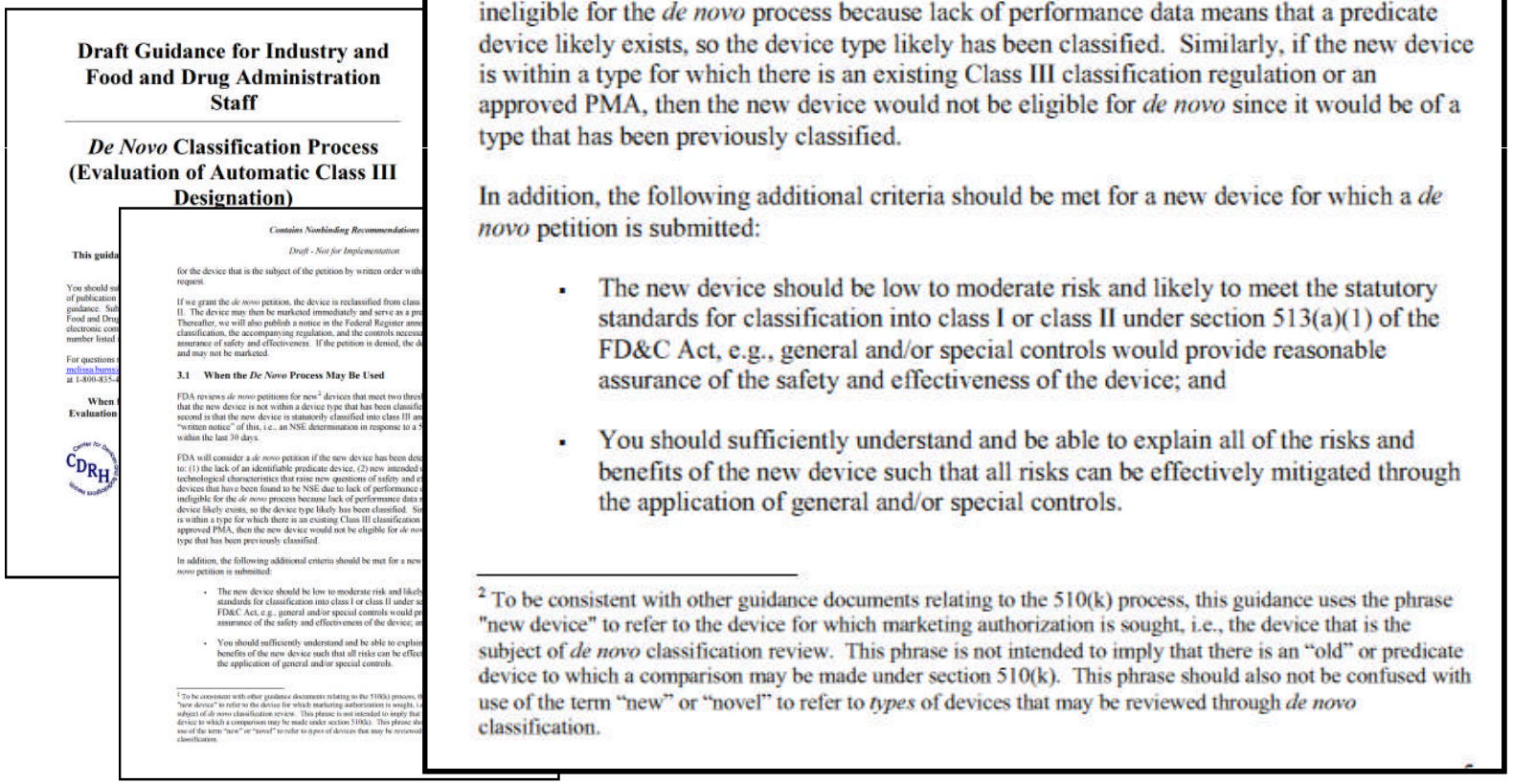
For questions regarding this document, contact Melissa Burns, 301-796-5616, melissa.burns@fda.hhs.gov or CBER's Office of Communication, Outreach and Development at 1-800-835-4709 or 301-827-1800.

When final, this document will supersede "New Section 513(f)(2) - Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff" dated February 19, 1998.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Office of In Vitro Diagnostic Device Evaluation and Safety

Center for Biologics Evaluation and Research

De Novo Gu



Draft Guidance for Industry and Food and Drug Administration Staff

De Novo Classification Process (Evaluation of Automatic Class III Designation)

Contains Nonbinding Recommendations

Draft - Not for Implementation

3.1 When the *De Novo* Process May Be Used

FDA reviews *de novo* petitions for new[2] devices that meet two threshold criteria. The first is that the new device is not within a device type that has been classified based on risk. The second is that the new device is statutorily classified into class III and FDA has provided "written notice" of this, i.e., an NSE determination in response to a 510(k) submission, within the last 30 days.

FDA will consider a *de novo* petition if the new device has been determined to be NSE due to: (1) the lack of an identifiable predicate device, (2) new intended use, or (3) different technological characteristics that raise new questions of safety and effectiveness. New devices that have been found to be NSE due to lack of performance data would generally be ineligible for the *de novo* process because lack of performance data means that a predicate device likely exists, so the device type likely has been classified. Similarly, if the new device is within a type for which there is an existing Class III classification regulation or an approved PMA, then the new device would not be eligible for *de novo* since it would be of a type that has been previously classified.

In addition, the following additional criteria should be met for a new device for which a *de novo* petition is submitted:

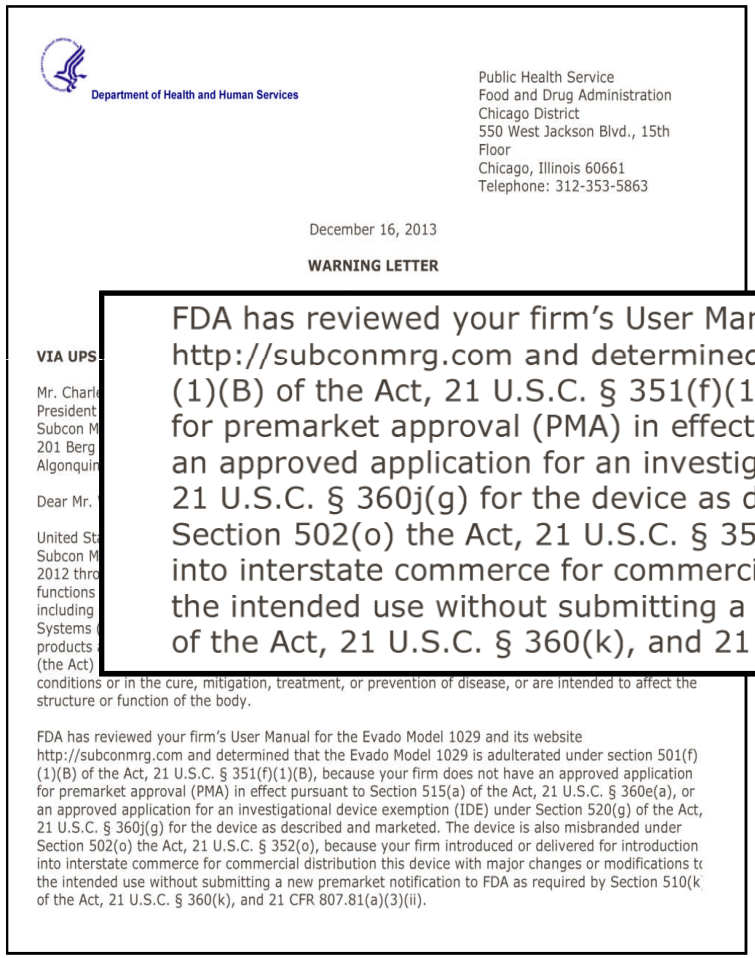
- The new device should be low to moderate risk and likely to meet the statutory standards for classification into class I or class II under section 513(a)(1) of the FD&C Act, e.g., general and/or special controls would provide reasonable assurance of the safety and effectiveness of the device; and
- You should sufficiently understand and be able to explain all of the risks and benefits of the new device such that all risks can be effectively mitigated through the application of general and/or special controls.

[2] To be consistent with other guidance documents relating to the 510(k) process, this guidance uses the phrase "new device" to refer to the device for which marketing authorization is sought, i.e., the device that is the subject of *de novo* classification review. This phrase is not intended to imply that there is an "old" or predicate device to which a comparison may be made under section 510(k). This phrase should also not be confused with use of the term "new" or "novel" to refer to *types* of devices that may be reviewed through *de novo* classification.

Post-Clearance Considerations

- General vs. Special Controls
- Quality System Regulation (GMP)
- Labeling Requirements
- Adverse Events
- Misbranding and Adulteration
- General vs. Specific Intended Use
- Pre-approval Commercialization Risks

Marketing Regulations



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

December 16, 2013

WARNING LETTER

VIA UPS

Mr. Charl
President
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Algonquin

Dear Mr.

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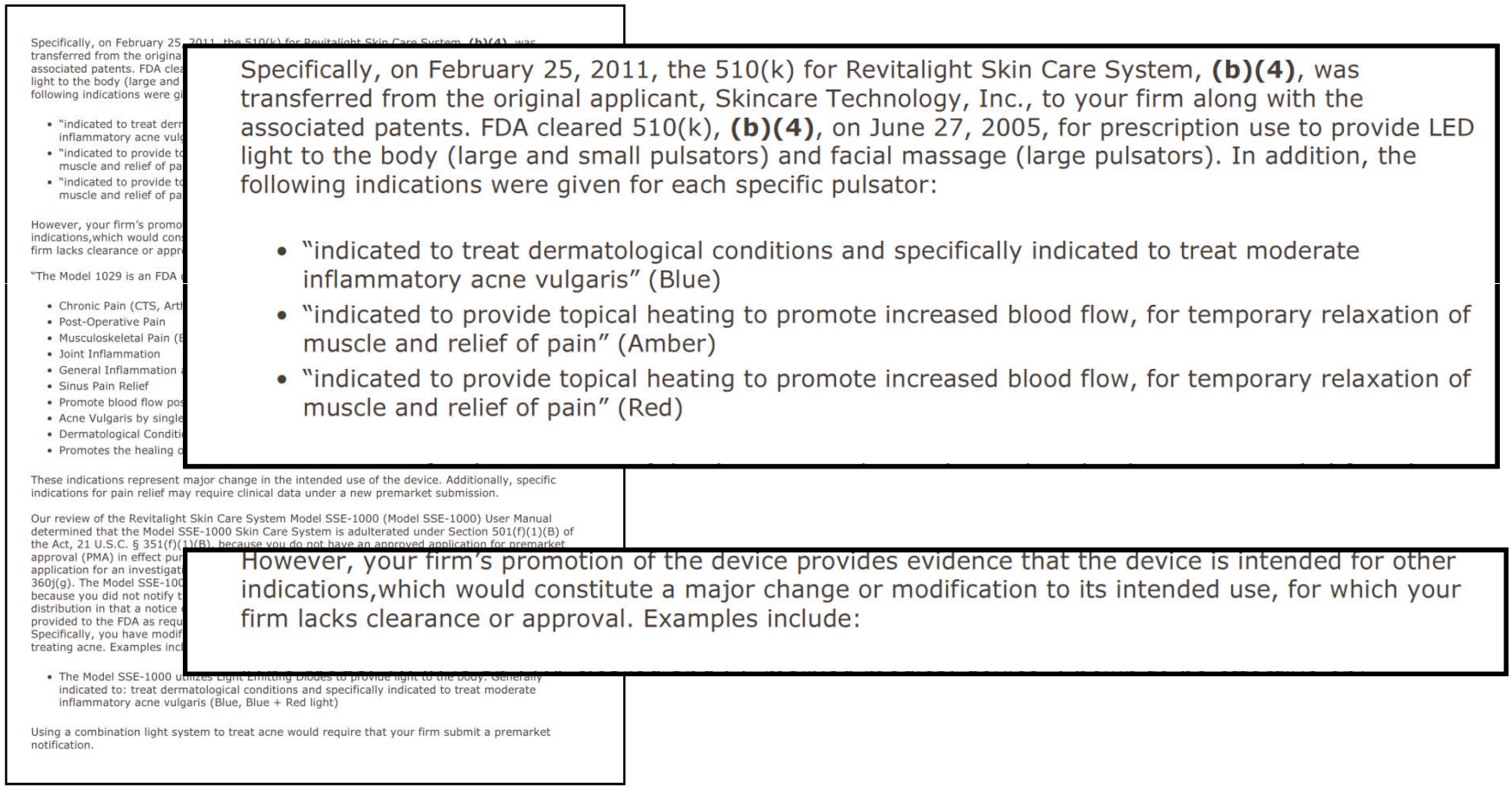
(the Act)
conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

FDA has reviewed your firm's User Manual for the Evado Model 1029 and its website http://subconmrg.com and determined that the Evado Model 1029 is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to Section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under Section 520(g) of the Act, 21 U.S.C. § 360j(g) for the device as described and marketed. The device is also misbranded under Section 502(o) the Act, 21 U.S.C. § 352(o), because your firm introduced or delivered for introduction into interstate commerce for commercial distribution this device with major changes or modifications to the intended use without submitting a new premarket notification to FDA as required by Section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR 807.81(a)(3)(ii).

FDA has reviewed your firm's User Manual for the Evado Model 1029 and its website http://subconmrg.com and determined that the Evado Model 1029 is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to Section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under Section 520(g) of the Act, 21 U.S.C. § 360j(g) for the device as described and marketed. The device is also misbranded under Section 502(o) the Act, 21 U.S.C. § 352(o), because your firm introduced or delivered for introduction into interstate commerce for commercial distribution this device with major changes or modifications to the intended use without submitting a new premarket notification to FDA as required by Section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR 807.81(a)(3)(ii).

Marketing Regulations (cont'd)

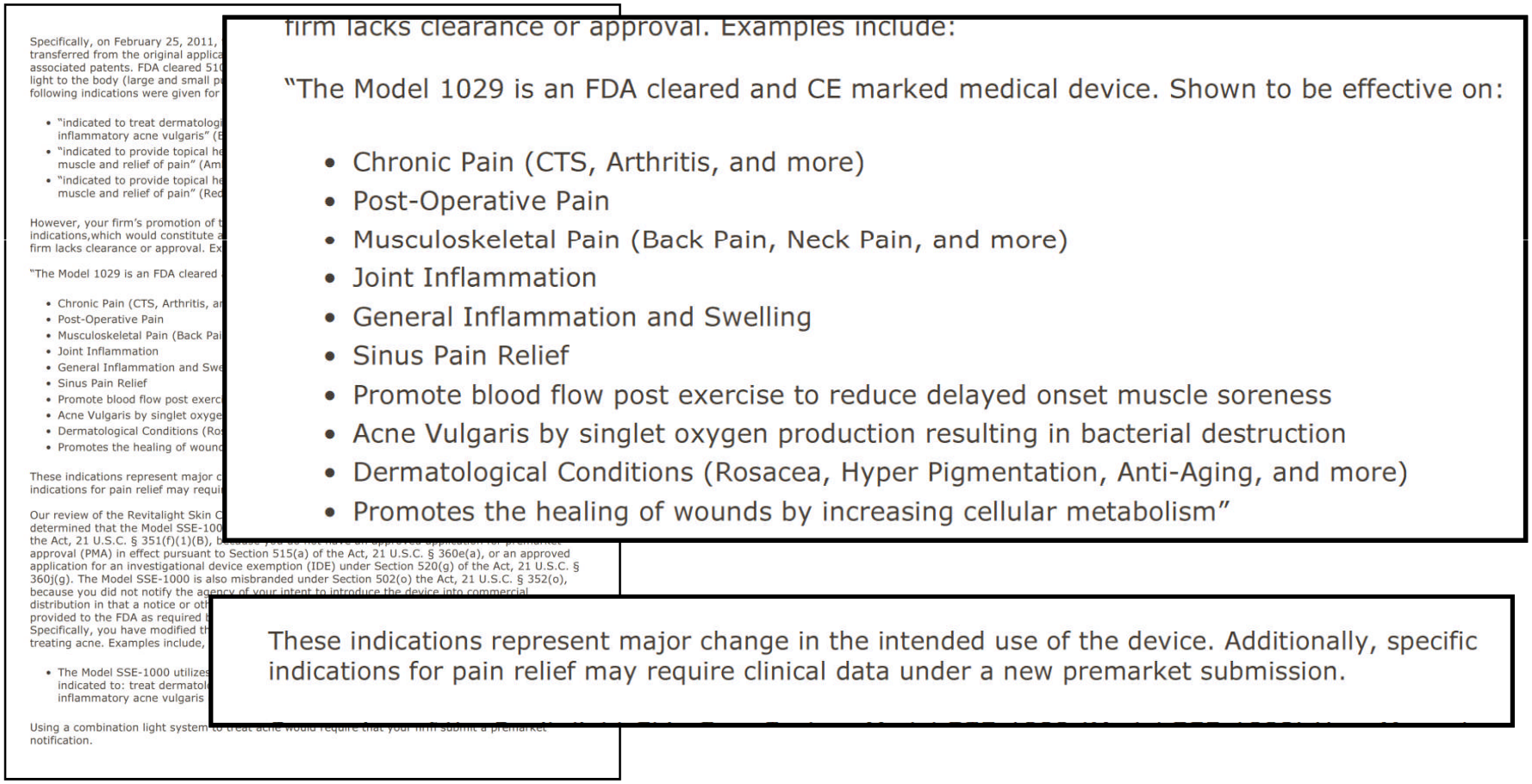


Specifically, on February 25, 2011, the 510(k) for Revitalight Skin Care System, **(b)(4)**, was transferred from the original applicant, Skincare Technology, Inc., to your firm along with the associated patents. FDA cleared 510(k), **(b)(4)**, on June 27, 2005, for prescription use to provide LED light to the body (large and small pulsators) and facial massage (large pulsators). In addition, the following indications were given for each specific pulsator:

- "indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris" (Blue)
- "indicated to provide topical heating to promote increased blood flow, for temporary relaxation of muscle and relief of pain" (Amber)
- "indicated to provide topical heating to promote increased blood flow, for temporary relaxation of muscle and relief of pain" (Red)

However, your firm's promotion of the device provides evidence that the device is intended for other indications,which would constitute a major change or modification to its intended use, for which your firm lacks clearance or approval. Examples include:

Marketing Regulations (cont'd)



firm lacks clearance or approval. Examples include:

"The Model 1029 is an FDA cleared and CE marked medical device. Shown to be effective on:

- Chronic Pain (CTS, Arthritis, and more)
- Post-Operative Pain
- Musculoskeletal Pain (Back Pain, Neck Pain, and more)
- Joint Inflammation
- General Inflammation and Swelling
- Sinus Pain Relief
- Promote blood flow post exercise to reduce delayed onset muscle soreness
- Acne Vulgaris by singlet oxygen production resulting in bacterial destruction
- Dermatological Conditions (Rosacea, Hyper Pigmentation, Anti-Aging, and more)
- Promotes the healing of wounds by increasing cellular metabolism"

These indications represent major change in the intended use of the device. Additionally, specific indications for pain relief may require clinical data under a new premarket submission.

Questions?

Mahnu Davar
mahnu.davar@aporter.com
(202) 942-6172

Philip Desjardins
philip.desjardins@aporter.com
(202) 942-5303