USER:	**GRAY, ILKA K (ixg)**
FOLDER:	**K080118 - 686 pages (FOI:01008151)**
COMPANY:	**ZELTIQ AESTHETICS (ZELTAEST)**
PRODUCT:	**POWERED LASER SURGICAL INSTRUMENT (GEX)**
SUMMARY:	**Product: ZELTIQ AESTHETICS CLN1 DERMAL COOLING DEVICE**

DATE REQUESTED:	**Wed Nov 10 24:00:00 2010**
DATE PRINTED:	**Thu Jan 20 09:31:55 2011**
Note:	**Releasable Version**

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SECTION 7. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

2. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	Zeltiq Aesthetics, Inc. 4698 Willow Road Pleasanton, CA 94588
TRADE NAME:	Zeltiq Cooling Device
COMMON NAME:	Skin Refrigerant
CLASSIFICATION NAME:	Laser instrument, surgical, powered
DEVICE CLASSIFICATION:	Class II, 21 CFR §878.4810
PRODUCT CODE	79 GEX – laser instrument, surgical, powered 89 IOL - pack, hot or cold, water circulating 89 ISA - massager, therapeutic, electric
PREDICATE DEVICE:	The Zeltiq CLN1 Dermal Cooling Device is substantially equivalent in intended use and mechanism of action to the Juniper CLN1 Dermal Cooling Device (K072152). The device is also substantially equivalent to the Cynosure Triactive Therapeutic massager (K030876).

MAY - 2 2008

SUBSTANTIALLY EQUIVALENT TO:
The Zeltiq CLN1 Dermal Cooling Device is substantially equivalent in intended use and mechanism of action to the Juniper CLN1 Dermal Cooling Device (K072152) and the Cynosure Triactive Therapeutic massager (K030876). The pager device used in the Zeltiq CLN1 Dermal Cooling Device is substantially equivalent to the Spacelabs Ultraview Waveform Pager System (K992749).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:
The Zeltiq CLN1 Dermal Cooling Device is a thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The device also includes the option of electrically powered or pulsatile vacuum massage.

SECTION 7. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

INDICATION FOR USE:

The Zeltiq CLN1 Dermal Cooling Device is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq CLN1 Dermal Cooling Device can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.

The Zeltiq Coupling Gels facilitate thermal contact of the Zeltiq CLN1 Dermal Cooling Device with a patient's skin by mitigating minor variances in device-to-skin contact.

TECHNICAL CHARACTERISTICS:

The Zeltiq CLN1 Dermal Cooling Device is a thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The optional massage feature uses electrically powered vibration or pulsatile vacuum, depending on the applicator.

PERFORMANCE DATA:

Testing confirms that the Zeltiq CLN1 Dermal Cooling Device can be used in an equivalent manner to the predicate devices.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The indications for use for the Zeltiq CLN1 Dermal Cooling Device are the same as for the predicate devices cited in this application. A technological comparison and bench testing demonstrate that the Zeltiq CLN1 Dermal Cooling Device is functionally equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2008

Zeltiq Aesthetics
% Mr. Donald V. Johnson
VP, Operations, Quality and
Regulatory Affairs
4698 Willow Road
Pleasanton, California 94588

Re: K080118
Trade/Device Name: Zeltiq CLN1 Dermal Cooling Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: April 25, 2008
Received: April 28, 2008

Dear Mr. Johnson:

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.

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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K080118

Device Name: Zeltiq CLN1 Dermal Cooling Device

Indications for Use:
The Zeltiq CLN1 Dermal Cooling Device is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq CLN1 Dermal Cooling Device can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.

The Zeltiq Coupling Gels facilitate thermal contact of the Zeltiq CLN1 Dermal Cooling Device with a patient's skin by mitigating minor variances in device-to-skin contact.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of 1

510(k) Number K080118

Document Cover Sheet:

Date of Submission:	15-JAN-2008
Description:	ZELTIQ AESTHETICS CLN1 DERMAL COOLING DEVICE
Date of Scan:	04-FEB-2009
Document Prep:	MH 2/4/09
Scanner:	MH 2/4/09
Image Quality Reviewer:	

K080118-K6748

FSR0701-000

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Total separator pages: 44				

QC Signature

QC Bar Code Sticker

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2008

Zeltiq Aesthetics
% Mr. Donald V. Johnson
VP, Operations, Quality and
Regulatory Affairs
4698 Willow Road
Pleasanton, California 94588

Re: K080118
Trade/Device Name: Zeltiq CLN1 Dermal Cooling Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
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Received: April 28, 2008

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Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K080118

Device Name: Zeltiq CLN1 Dermal Cooling Device

Indications for Use:
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of 1

510(k) Number K080118

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 31, 2008

ZELTIQ AESTHETICS
4698 WILLOW ROAD
PLEASANTON, CA 94588
ATTN: DONALD V. JOHNSON

510(k) Number: K080118
Product: ZELTIQ AESTHETICS CLN1 DERMAL COOLING DEVICE

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.
Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40
9200 Corporate Blvd.
Rockville, Maryland 20850

February 28, 2008

ZELTIQ AESTHETICS
4698 WILLOW ROAD
PLEASANTON, CA 94588
ATTN: DONALD V. JOHNSON

510(k) Number: K080118
Product: ZELTIQ AESTHETICS CLN1 DERMAL COOLING DEVICE

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may revi this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.
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If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40
9200 Corporate Blvd.
Rockville, Maryland 20850

February 01, 2008

ZELTIQ AESTHETICS
4698 WILLOW ROAD
PLEASANTON, CA 94588
ATTN: DONALD V. JOHNSON

510(k) Number: K080118
Received: 31-JAN-2008
Product: ZELTIQ AESTHETICS CLN1 DERMAL COOLING DEVICE

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federa Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited abov Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you whe the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medica device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, th Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/cdrh/mdufma/index.html for more information regardin fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) nee to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf.

A new provision of the Food and Drug Administration Amendments Act of 2007, 42 U.S.C. 282(j)(5)(B), requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany all 510(k)/HDE/PMA submissions on or after December 26, 2007. You are responsible for registering certain device clinical trials in the Clinical Trials Data Bank (http://prsinfo.clinicaltrials.gov). If your submission does not include FDA Form 3674, please send 2 hardcopies of the completed certification form referencing the submission number identified above. Additional information about the new certification

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form may be found at the following link to the Federal Register Notice (http://www.fda.gov/OHRMS/DOCKETS/98fr/07-6023.htm).

Please note the following documents as they relate to 510(k) review:
1)Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1655.pdf. Please refer to this guidance for information on a formalized interactive review process.
2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditiona or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electron copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/" If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Heal

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401
9200 Corporate Blvd.
Rockville, Maryland 20850

January 17, 2008

ZELTIQ AESTHETICS
4698 WILLOW ROAD
PLEASANTON, CA 94588
ATTN: DONALD V. JOHNSON

510(k) Number: K080118
Received: 17-JAN-2008
User Fee ID Number: 6034340
Product: ZELTIQ AESTHETICS CLN1 DERMAL COOLING

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full therefore, the file has been placed on hold. When your user fee paymen has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. Please send a check to one of the addresses listed below:

By Regular Mail	By Private Courier(e.g.,Fed Ex, UPS, etc.)
Food and Drug Administration P.O. Box 956733 St. Louis, MO 63195-6733.	U.S. Bank 956733 1005 Convention Plaza St. Louis, MO 63101 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User F Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (240)276-4025 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) wi be deleted from the system. Additional information on user fees and ho to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

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In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-fee number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Christina Zeender at Christina.Zeender@fda.hhs.gov. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers address above.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Office of Device Evaluation
Center for Devices and
Radiological Health

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K080118

510(k) PREMARKET NOTIFICATION FOR THE ZELTIQ CLN1 DERMAL COOLING DEVICE

APPLICANT

Zeltiq Aesthetics, Inc
4698 Willow Road
Pleasanton, CA 94588

OFFICIAL CORRESPONDENT

Donald Johnson
Vice President, Operations, Regulatory, & Quality Affairs
Phone (b)(4) (b)(4)
Fax (b)(4) (b)(4)
e-mail: (b)(4) (b)(4)

SU
H

510(k) PREMARKET NOTIFICATION FOR THE ZELTIQ CLN1 DERMAL COOLING DEVICE

TABLE OF CONTENTS

FIGURES AND TABLES

ATTACHMENTS

1. MEDICAL DEVICE USER FEE COVER SHEET (FORM FDA 3601)

Form Approved: OMB No 0910-511 Expiration Date: January 31, 2010 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

ZELTIQ AESTHETICS, INC.
4698 WILLOW ROAD
Pleasanton CA 94588
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4)

2. CONTACT NAME
Donald Johnson

2.1 E-MAIL ADDRESS
(b)(4)

2.2 TELEPHONE NUMBER (include Area code)
(b)(4)

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
(b)(4)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: SBD088071

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4)
03-Jan-2008

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

https://fdasfinapp8.fda.gov/OA_HTML/mdufmaCScdCfgItemsPopup.jsp?vcname=Donald... 1/3/2008

2. CDRH PREMARKET REVIEW SUBMISSION COVER SHEET (FORM FDA 3514)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
1/15/2008	MD6031965-956733	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Zeltiq Aesthetics, Inc.	Establishment Registration Number *(if known)*		
Division Name *(if applicable)*	Phone Number *(including area code)* (b)(4)		
Street Address 4698 Willow Road	FAX Number *(including area code)* (b)(4)		
City Pleasanton	State / Province CA	ZIP/Postal Code 94588	Country USA
Contact Name Donald V. Johnson			
Contact Title Vice President, Operations, Regulatory, and Quality Affairs	Contact E-mail Address (b)(4)		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)* ( )		
Street Address	FAX Number *(including area code)* ( )		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Sterilization
  - [ ] Packaging
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Response to FDA correspondence:

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Repose to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [x] Other Reason *(specify)*:
  Updated device with new software and accessories

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	79 GEX	2	89 IOL	3	89 ISA	4	74 MSX
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K072152	1	CLN1 Dermal Cooling Device	1	Zeltiq Aesthetics, Inc.
2	K030876	2	Cynosure Triactive Therapeutic massager	2	CYNOSURE, INC
3	K023231	3	ElfCare	3	MediSeb
4	K992749	4	Spacelabs Ultraview Waveform Pager System	4	SPACELABS MEDICAL, INC
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

	Trade or Proprietary or Model Name for This Device		Model Number
1	Zeltiq Aesthetics CLN1 Dermal Cooling Device	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K072152	2 K063715	3 K060407	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code
79 GEX

C.F.R. Section *(if applicable)*
21 CFR 878.4810

Device Class

- [ ] Class I
- [x] Class II
- [ ] Class III
- [ ] Unclassified

Classification Panel
General & Plastic Surgery

Indications *(from labeling)*

The Zeltiq CLN1 Dermal Cooling Device is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include: skin cooling as a local anesthetic for procedures that induce minor local discomfort, localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms and improvement in local circulation and temporary reduction in the appearance of cellulite, relief of minor muscle aches, pain, and spasm, while utilizing the optional massage feature.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name Zeltiq Aesthetics, Inc.		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)* ((b)(4) (b)(4)	
Street Address 4698 Willow Road		FAX Number *(including area code)* ((b)(4) (b)(4)	
City Pleasanton		State / Province CA	ZIP/Postal Code 94588 / Country USA
Contact Name Donald V. Johnson	Contact Title Vice President, Operations, Regulatory and Quality Affairs	Contact E-mail Address (b)(4) (b)(4)	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)* ( )	
Street Address		FAX Number *(including area code)* ( )	
City		State / Province	ZIP/Postal Code / Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)* ( )	
Street Address		FAX Number *(including area code)* ( )	
City		State / Province	ZIP/Postal Code / Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 10993-5	ISO	Biological Evaluation of Medical Devices-Part 5: Tests for in vitro cytotoxicit	2	1/1/1999
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

3. REQUIREMENTS FOR CLINICAL TRIALS (FORM FDA3674)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

Form Approved: OMB No. 0910-0616
Expiration Date: 06-30-2008
See OMB Statement on Reverse

SPONSOR/APPLICANT/SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER: Zeltiq Aesthetics, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES: January 15, 2008

3. ADDRESS (*Number, Street, State, and Zip Code*): 4698 Willow Road, Pleasanton, CA 94588

4. TELEPHONE AND FAX NUMBER (*Include Area Code*)
(T) (b)(4)
(F) (b)(4)

PRODUCT INFORMATION

5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(*Attach extra pages as necessary*)

Dermal Cooling Device, CLN1

APPLICATION/SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (*if number previously assigned*)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT/INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES
(*See instructions for additional information and explanation*)

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN # 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
(*Attach extra pages as necessary*)

NCT Number(s)

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (SIGN) Donald V. Johnson	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN #11 Donald V. Johnson Vice-President of Operations, Quality, and Regulatory Affairs
13. ADDRESS *(Number, Street, State, and Zip Code) (of person identified in #11 & 12)* 4698 Willow Road Pleasanton, CA 94588	14. TELEPHONE AND FAX NUMBER *(Include Area Code)* (T) (b)(4) (F) (b)(4)
15. DATE OF CERTIFICATION January 15, 2008	

Paperwork Reduction Act Statement

Public Reporting Burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Form No. FDA 3674
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. Name of Sponsor/Applicant/Submitter - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.

2. Date - This is the date of the application/submission which the certification accompanies.

3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.

5. Product Information - For Drugs/Biologics: Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/ submission. Include all available names by which the product is known.
For Devices: Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

6. Type of Application/Submission - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."

7. IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number - If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

8. Serial Number - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.

9. Certification - This section contains three different check-off boxes.

Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

10. National Clinical Trial (NCT) Numbers - If you have checked Box C in # 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

11. Signature of Sponsor/Applicant/Submitter or an Authorized Representative - The person signing the certification must sign in this field.

12. Name and Title of Person Who Signed in #11. - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/ submitter.

13. & 14. & 15. - Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 12. Provide the date the certification is signed. This date may be different from the date provided in #2.

4. STANDARDS DATA REPORT FOR 510(K)S (FORM FDA 3654)

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-5, Biological Evaluation of Medical Devices-Part 5: Tests for in vitro cytotoxicity, revision 2, 1/1/1999

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 018	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: #G95-1 : Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d]. www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-5, Biological Evaluation of Medical Devices-Part 5: Tests for in vitro cytotoxicity, revision 2, 1/1/1999

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Test procedures	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED♦
Test on extracts

DESCRIPTION
See ATTACHMENT 15-1

JUSTIFICATION
See ATTACHMENT 15-1

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

FORM FDA 3654 (9/07) Page 2

5. COVER LETTER

January 15, 2008

510(k) Document Mail Center (HFZ-401)
Food and Drug Administration
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD 20850

RE: Premarket Notification for the Zeltiq CLN1 Dermal Cooling Device

APPLICANT Zeltiq Aesthetics, Inc.
4698 Willow Road
Pleasanton, CA 94588

OFFICIAL CORRESPONDENT Donald Johnson
Vice President, Operations, Regulatory, & Quality Affairs
Phone (b)(4) (b)(4)
Fax (b)(4) (b)(4)
e-mail: (b)(4) (b)(4)

DEVICE CLASSIFICATION Class II, 21 CFR §878.4810

PRODUCT CODES 79 GEX – laser instrument, surgical, powered
89 IOL - pack, hot or cold, water circulating
89 ISA – massager, therapeutic, electric

Dear CDRH Staff:

Please note that as of July 31, 2007, Juniper Medical, Inc. changed the company name to Zeltiq Aesthetics, Inc. Previous 510k submissions were made under the name of Juniper Medical.

Pursuant to the provision of Section 510(k) of the Federal Food, Drug and Cosmetic Act and the Safe Medical Devices Act of 1990, notification is made of the intention of Zeltiq Aesthetics, Inc. to market and distribute the Zeltiq CLN1 Dermal Cooling Device, an upgrade to the recently cleared Juniper CLN1 Dermal Cooling Device (K072152, cleared September 7, 2007). This upgraded Zeltiq CLN1 Dermal Cooling Device includes:

- a vacuum applicator that provides pulsatile massage,
- use of a (b)(4) (b)(4) with the Zeltiq gel as the interface between the applicator sleeve and the skin,

K16

- hardware modifications to include a transmitter system that supports an accessory pager, and
- software modifications to provide:
  - (b)(4) (b)(4) (b)(4) (b)(4)
  - (b)(4) (b)(4) and
  - an optional pager for notification of device status (e.g., system error, treatment complete).

The upgrade is substantially equivalent in intended use and mechanism of action to the Juniper CLN1 Dermal Cooling Device (K072152), the Juniper Cooling Device XTRA (K063715), the Juniper Cooling Device (K060407), and the MediSeb ElfCare thermal therapy device for both hot and cold applications (K023231). The device is also substantially equivalent to the Cynosure Triactive Therapeutic massager (K030876). The pager incorporated into the upgrade is substantially equivalent to the Spacelabs Ultraview Waveform Pager System (K992749).

Substantial equivalence was determined on a descriptive basis by comparing the technological characteristics of the devices (see Section1). The descriptive rationale for substantial equivalence is supported by bench testing (see Section14).

This submission has been formatted per the recommendations made by the Agency in the Guidance: "Format for Traditional and Abbreviated 510(k)s", issued on August 12, 2005. Zeltiq regards information provided in support of this premarket notification to be confidential and proprietary and afforded such protection under 21CFR 807.95 and other applicable regulations and statutes. In accordance with the Safe Medical Devices Act of 1990, a 510(k) Summary of Safety and Effectiveness is included in this notification. A CD with an electronic version of this submission is enclosed for the reviewers' convenience.

We trust that this submission will be satisfactory for review. If there are any questions, or if additional information is required, please contact me at (b)(4) (b)(4) or by email at (b)(4) (b)(4)

Sincerely,

Donald Johnson
Vice President, Operations, Regulatory, and Quality Affairs
Zeltiq Aesthetics, Inc.

6. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Zeltiq CLN1 Dermal Cooling Device

Indications for Use:
The Zeltiq CLN1 Dermal Cooling Device is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq CLN1 Dermal Cooling Device can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and / or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the relief of minor muscle aches, pain, and spasm and for the improvement in local circulation and temporary reduction in the appearance of cellulite.

The Zeltiq Coupling Gels facilitate thermal contact of the Zeltiq CLN1 Dermal Cooling Device with a patient's skin by mitigating minor variances in device-to-skin contact.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

7. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	Zeltiq Aesthetics, Inc. 4698 Willow Road Pleasanton, CA 94588
TRADE NAME:	Zeltiq Cooling Device
COMMON NAME:	Skin Refrigerant
CLASSIFICATION NAME:	Laser instrument, surgical, powered
DEVICE CLASSIFICATION:	Class II, 21 CFR §878.4810
PRODUCT CODE	79 GEX – laser instrument, surgical, powered 89 IOL - pack, hot or cold, water circulating 89 ISA - massager, therapeutic, electric
PREDICATE DEVICE:	The Zeltiq CLN1 Dermal Cooling Device is substantially equivalent in intended use and mechanism of action to the Juniper CLN1 Dermal Cooling Device (K072152). The device is also substantially equivalent to the Cynosure Triactive Therapeutic massager (K030876).

SUBSTANTIALLY EQUIVALENT TO:

The Zeltiq CLN1 Dermal Cooling Device is substantially equivalent in intended use and mechanism of action to the Juniper CLN1 Dermal Cooling Device (K072152) and the Cynosure Triactive Therapeutic massager (K030876). The pager device used in the Zeltiq CLN1 Dermal Cooling Device is substantially equivalent to the Spacelabs Ultraview Waveform Pager System (K992749).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Zeltiq CLN1 Dermal Cooling Device is a thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The device also includes the option of electrically powered or pulsatile vacuum massage.

SECTION 7. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

INDICATION FOR USE:

The Zeltiq CLN1 Dermal Cooling Device is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq CLN1 Dermal Cooling Device can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and / or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the relief of minor muscle aches, pain, and spasm and for the improvement in local circulation and temporary reduction in the appearance of cellulite.

The Zeltiq Coupling Gels facilitate thermal contact of the Zeltiq CLN1 Dermal Cooling Device with a patient's skin by mitigating minor variances in device-to-skin contact.

TECHNICAL CHARACTERISTICS:

The Zeltiq CLN1 Dermal Cooling Device is a thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The optional massage feature uses electrically powered vibration or pulsatile vacuum, depending on the applicator.

PERFORMANCE DATA:

Testing confirms that the Zeltiq CLN1 Dermal Cooling Device can be used in an equivalent manner to the predicate devices.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The indications for use for the Zeltiq CLN1 Dermal Cooling Device are the same as for the predicate devices cited in this application. A technological comparison and bench testing demonstrate that the Zeltiq CLN1 Dermal Cooling Device is functionally equivalent to the predicate devices.

8. TRUTHFUL AND ACCURATE STATEMENT

Pursuant to 21 CFR 807.87(j) I certify that in my capacity as Vice President, Operations, Quality, and Regulatory Affairs of Zeltiq Aesthetics, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Donald Johnson 1/15/08

Donald Johnson Date

Vice President, Operations, Quality, & Regulatory Affairs

9. CLASS III SUMMARY AND CERTIFICATION

The Zeltiq CLN1 Dermal Cooling Device is a Class II medical device regulated under 21 CFR §878.4810. Thus, the Class III Summary and Certification requirement as described in 21 CFR §807.87(j) and §807.94 does not apply to this device and submission.

10. FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

The requirement for financial certification or disclosure requirement as described in 21 CFR §807.87(i) does not apply to this submission.

11. DECLARATION OF CONFORMITY & SUMMARY REPORTS

This submission is a traditional 510(k) submission. The requirement for a declaration of conformity and a summary report of testing is not required.

12. EXECUTIVE SUMMARY

Topical application of heat and cold (thermotherapy) is commonly used to ameliorate the pain and inflammatory damage caused by an injury. Thermotherapy has been shown to:

- decrease muscle spasm secondary to musculoskeletal pathology or nerve root irritation; and
- cause analgesia.

In general, the goal of cold application as a therapeutic modality is related to prevention of tissue damage and reduction of the inflammatory products in the acute stage of an injury. Heat is usually applied after the acute phase, causing capillary dilation and encouraging blood flow to the tissue. Similarly, application of massage can alleviate minor muscle aches and pains and may temporarily reduce the appearance of cellulite.

The Juniper Cooling Device was originally cleared for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments (K060407). The intended use was subsequently modified with the Juniper Cooling Device XTRA (K063715) to include localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms, as well as for use of the optional massage function for the relief of minor muscle aches, pain, and spasm and for the improvement in local circulation and temporary reduction in the appearance of cellulite.

Another series of device upgrades were implemented in the Juniper CLN1 Dermal Cooling Device (K072152) to enhance portability, simplify the user interface, provide a belt applicator with a larger treatment area, and provide a disposable sleeve both as an interface (b)(4) (b)(4) (b)(4) (b)(4)

The current submission for the Zeltiq CLN1 Dermal Cooling Device includes the following design enhancements:

- a vacuum applicator with pulsatile massage,
- use of a (b)(4) (b)(4) with the Zeltiq gel as the interface between the applicator sleeve and the skin,
- hardware modifications to include a transmitter system that supports an accessory pager, and
- software modifications with:
  - (b)(4) (b)(4)
  - a pager for notification of device status (e.g., system error, treatment complete).

There is no change to the intended use, however, in this premarket notification for the Zeltiq CLN1 Dermal Cooling Device.

12.1. INTENDED USE

The Zeltiq CLN1 Cooling Device is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq CLN1 Dermal Cooling Device can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and / or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the relief of minor muscle aches, pain, and spasm and for the improvement in local circulation and in the temporary reduction in the appearance of cellulite.

The Zeltiq Coupling Gels facilitate thermal contact of the Zeltiq CLN1 Dermal Cooling Device with a patient's skin by mitigating minor variances in device-to-skin contact.

12.2. PREDICATE DEVICE

The Zeltiq CLN1 Dermal Cooling Device is substantially equivalent in intended use and mechanism of action to the Juniper CLN1 Dermal Cooling Device (K072152) and the MediSeb ElfCare thermal therapy device (K023231). The device is also substantially equivalent to the Cynosure Triactive Therapeutic massager (K030876). The pager device used in the Zeltiq CLN1 Dermal Cooling Device is substantially equivalent to the Spacelabs Ultraview Waveform Pager System (K992749).

Table 1 compares the similarities and differences of the Zeltiq CLN1 Dermal Cooling Device and its predicates.

Table 1. Substantial Equivalence Matrix for the Zeltiq CLN1 Dermal Cooling Device

Element	Zeltiq CLN 1 Dermal Cooling Device (subject of this submission)	Juniper CLN1 Dermal Cooling Device K072152	ELFCare™ K023231	Cynosure Triactive Therapeutic Massage System K030876
Indications for Use	• … used to minimize pain and thermal injury during laser and dermatological treatments…	• same		
	• Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort;	• same		
	For Hot/Cold Therapy…	For Hot/Cold Therapy…		
	• localized thermal therapy (hot or cold) to minimize pain for post traumatic and / or post surgical pain;	• same	• same	
	• for temporary relief of minor aches and pains and muscle spasms;	• same	• same	• same
	Massage Therapy…	Massage Therapy…		Massage Therapy…
	• temporary improvement in local circulation;	• same		• same
	• temporarily reduces the appearance of cellulite.	• same		• same
Principle of Operation				
Skin cooling / heating mechanism	Flat or cupped applicator, applied topically	Flat applicator, applied topically	Flat applicator, applied topically	Flat applicator, with slightly protruding rollers at the outer edges, applied topically
Applicator interface surface area	(b)(4) (b)(4)	• same	6,500 mm^2	Variable, depending on attachment chosen

Element	Zeltiq CLN 1 Dermal Cooling Device (subject of this submission)	Juniper CLN1 Dermal Cooling Device K072152	ELFCare™ K023231	Cynosure Triactive Therapeutic Massage System K030876
Temperature control mechanism	Thermoelectric	• same	• same	Laser
Treatment temperatures	(b)(4) (b)(4)	• same	-(10)°C to 42°C	20 °C to 60°C (estimated)
Maximum recommended application time	(b)(4) (b)(4)	• same	• same	Recommended treatment time: 30 minutes; maximum treatment duration not specified
Massage Feature	Yes – electrically powered (vibration or pulsatile vacuum)	Yes – electrically powered (vibration)	No	Yes – electrically powered (pulsatile vacuum)
Design Features				
General Design	Unit attached to a hand-held patient interface; optional strap available for hands-free application	• same	Hands-free application with adjustable strap	Unit attached to a hand-held patient interface
Temperature accuracy	(b)(4) (b)(4)	• same	±1°C	unknown
Temperature display	Computer screen and LCD	• same	• same	LCD
Power Source	AC	• same	AC/Optional Battery	• same
Microprocessor controlled	Yes	• same	• same	• same
Safety Shut-off	Yes – auto shut off	• same	• same	Yes
Other Features				
Reusable	Yes	• same	• same	• same

Table 2. Substantial Equivalence Matrix for the Zeltiq CLN1 Paging Device

Element	Zeltiq CLN 1 Dermal Cooling Device (subject of this submission)	Spacelabs Ultraview Waveform Pager System (K992749)
Indications for Use	To provide a secondary means of notification and display of system status (e.g., procedure completion, system error) to mobile health care providers	• …to provide a secondary means of notification and display of patient alarm information to mobile health care providers • …for use in real-time monitoring of routine patient status and alarm events
Principle of Operation		
Server	The control unit acts as the server that collects and formats monitoring data to send to the transmitter via an RS232 port	A server collects and formats monitoring data
Transmitter	(b)(4) (b)(4) Inc. that operates on UHF frequency (420 – 470 MHz) with synthesized frequency and modulation	Any Flex-Binary paging transmitter that meets site requirement and operates in the protected 929-931 MHz paging band
Receiver (Pager)	Battery operated alphanumeric pager by (b)(4) (b)(4) that stores up to 99 messages.	Battery operated, alphanumeric pager by Motorola (CP1250) that stores up to 43 messages
Design Features		
Transmitter	Messages delivered "immediately"	Notification occurs within 4 to 8 seconds after an alarm event (for telemetry and hardwired patients)
Receiver (Pager)	• Stores up to 99 messages • Displays up to 4 lines of text, 200 character display • Backlighting • Vibrate and beep alert modes • Operates on a single AAA battery • Low battery indicator	• Stores up to 43 messages • Displays up to 8 lines of text, zooms in to 4 lines for larger view. • Backlighting • User selectable alerts • Operates on a single AAA battery • Low battery indicator
Other Features		
Reusable	Yes	Yes

12.3. PERFORMANCE STANDARDS

No performance standards have been established by the Agency to date that apply to this device.

12.4. BENCH & ANIMAL TESTING

Bench testing and software validation demonstrate that the Zeltiq CLN1 Dermal Cooling Device (b)(4) (b)(4) and (b)(4) (b)(4) The testing also demonstrates that the optional massage and pager features work within design specification parameters.

13. GENERAL DEVICE DESCRIPTION

Like the earlier version of the device, the Zeltiq CLN1 Dermal Cooling Device is a thermoelectric device that applies a user selected treatment profile in a controlled manner to a treatment site. The Zeltiq CLN1 Dermal Cooling Device that is the subject of this submission includes design enhancements that provide:

- a vacuum applicator with pulsatile massage, and
- use of a (b)(4) with the Zeltiq gel as the interface between the applicator sleeve and the skin,
- hardware modification to include a transmitter system that supports an accessory pager, and
- software modifications with:
  - (b)(4)
  - (b)(4)
  - a pager for notification of device status (e.g., system error, treatment complete).

13.1. SPECIFIC DEVICE DESCRIPTION

The Zeltiq CLN1 Dermal Cooling Device consists of the following components:

- Applicator;
- Applicator Sleeves;
- Portable control unit containing the control and power systems; and
- User Interface.

Like the earlier version of the device, the Zeltiq CLN1 Dermal Cooling Device is a thermoelectric device that applies a user selected treatment profile in a controlled manner to a treatment site. The Zeltiq CLN1 Dermal Cooling Device that is the subject of this submission includes design enhancements that provide:

1. An alternate applicator design as an accessory to the Zeltiq CLN1 Dermal Cooling Device. This applicator includes the use of a vacuum to provide the massage feature. The vacuum applicator also draws tissue into the applicator during the cooling treatment.
2. (b)(4) (b)(4)

---

1 (b)(4) (b)(4)
(b)(4) (b)(4)

3. Hardware modification to include a transmitter system for support of an accessory pager that provides a secondary means of notification and display of system status to mobile health care providers, and
4. Software upgrades to include enhancements to the user interface including feedback on:
   - (b)(4)
   - (b)(4)
   - the device status during treatment, such as when the treatment is complete or if a system error occur, through use of an optional pager that notifies the user.

There are no changes to the belt applicator, and its disposable sleeve, or the coupling gels

13.2. THE APPLICATOR

Two applicator designs are available for use with the Zeltiq CLN1 Dermal Cooling Device, the articulated belt applicator (3-Link and 5-Link) cleared in the previous 510(k) for the device (K072152) and the vacuum applicator that is the subject of this 510(k). Both applicators apply cooling or warming to the treatment site, and both applicators provide the massage function. The articulated belt applicator provides vibrational massage; the vacuum applicator provides pulsatile massage.

The vacuum applicator draws the skin up between two independently controlled aluminum plates. The construction and functionality of the plates are similar to the links of the articulated belt. Each plate houses an independently controlled thermoelectric cooler (TEC) that provides the cooling or warming at the skin surface. Vacuum is maintained to hold the tissue in place while the treatment is applied. Figure 1 shows the vacuum applicator.

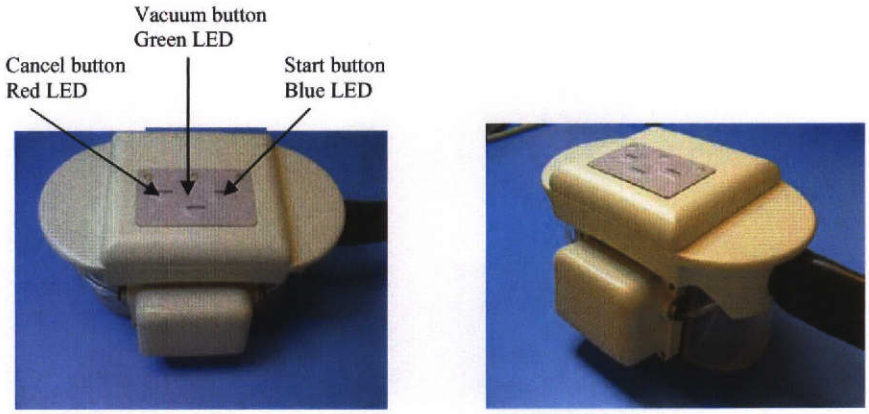


Figure 1 - Vacuum applicator

The applicator is connected to the control unit by a flexible cable. The cable, like that of the articulated belt applicator, incorporates the tubing for liquid exchange between the thermoelectric coolers and the chiller housed in the control unit, as well as electrical connections.

The top of the vacuum applicator includes three buttons and LED indicators. The buttons are provided as an optional method to initiate or terminate treatment and to start and stop the vacuum pump. A blue LED illuminates when the device is ready to start a treatment application and flashes during treatment. If a system error is detected, the treatment is automatically terminated and a red LED illuminates. Operation of the vacuum pump is indicated by a green LED above the button used to start and stop the vacuum.

13.3. THE APPLICATOR SLEEVE

The (b)(4) (b)(4) (b)(4) (b)(4) The sleeve is attached to the applicator prior to use of the Zeltiq CLN1 Dermal Cooling Device. The disposable sleeve provides an interface and a physical barrier between the applicator and the skin. (See Figure 2.) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) Sleeves are disposable, single patient use items. (b)(4) (b)(4) in a (b)(4) (b)(4) (b)(4) (b)(4).

Figure 2 – Applicator sleeve placed in vacuum applicator.

13.4. CONTROL UNIT

The control unit is a portable device that can be easily positioned prior to treatment. The control unit includes the user interface, chiller, and control electronics. The control unit also includes a storage area for the applicator, disposable sleeves, and coupling gel.

The thermoelectric modules in the applicator are controlled and powered by an integrated controller console. As a safety feature, power to the applicator will shut off automatically if (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) The system has been tested for electrical safety through IEC60601 testing.

(b)(4) (b)(4) (b)(4) (b)(4)

There is no change to the controller and power supply for the Zeltiq CLN1 Dermal Cooling Device that is the subject of this submission.

13.4.1. USER INTERFACE

Control parameters for the Zeltiq CLN1 Dermal Cooling Device are entered through a user interface on a touch screen LCD. The touch screen and color display allow selection of the treatment profile and display of warnings and errors. During use, the device displays the current treatment condition (b)(4) (b)(4) at the applicator/skin interface, the preceding treatment condition, and the remaining treatment time on the user interface screen. There is no change to these aspects of the user interface for the Zeltiq CLN1 Dermal Cooling Device that is the subject of this submission.

Enhancements to the user interface have been included in the Zeltiq CLN1 Dermal Cooling Device. These (b)(4) (b)(4) (b)(4) (b)(4)

- (b)(4) (b)(4)
- (b)(4)

In addition, an optional paging system has been added to provide a secondary system to notify staff of system status such as: when a treatment session is cancelled, procedure completion or system error. The paging system consists of:

- The control unit, which collects and formats monitoring data to send to (b)(4) (b)(4)
- (b)(4) (b)(4)
-

13.4.2. DEVICE OPERATION

Complete instructions for use and principles of operation can be found in Section 15 of this submission. In brief, (b)(4) (b)(4) (b)(4) (b)(4), (b)(4) (b)(4)

(b)(4) (b)(4) (b)(4) (b)(4) by the system or a system error occurs.

13.5. INTENDED USE

The Zeltiq CLN1 Dermal Cooling Device is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq

CLN1 Dermal Cooling Device can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and / or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the relief of minor muscle aches, pain, and spasm and for the improvement in local circulation and temporary reduction in the appearance of cellulite.

The Zeltiq Coupling Gels facilitate thermal contact of the Zeltiq CLN1 Dermal Cooling Device with a patient's skin by mitigating minor variances in device-to-skin contact.

There is no change to the intended use of the device.

14. SUBSTANTIAL EQUIVALENCE DISCUSSION

The Zeltiq CLN1 Dermal Cooling Device is an upgrade to the recently cleared skin cooling device, the Juniper CLN1 Dermal Cooling Device (K072152). The design upgrade now includes the use of a vacuum applicator, enhanced user interface features, and an (b)(4) (b)(4) The Zeltiq CLN1 Dermal Cooling Device is substantially equivalent in intended use and mechanism of action to the Juniper CLN1 Dermal Cooling Device (K072152) and the MediSeb ElfCare thermal therapy device for both hot and cold applications (K023231). The device is also substantially equivalent to the Cynosure Triactive Therapeutic massager (K030876) as it includes an electrically powered, pulsatile massage feature for the temporary improvement in local circulation and the temporary reduction in the appearance of cellulite. Information on these substantially equivalent devices is provided in Attachment 14-1 and Attachment 14-2 of this premarket notification.

The 510(k) "Substantial Equivalence" Decision-Making Process in ODE Guidance Document #K86-3, Guidance on the CDRH Premarket Notification Review Program, was used to determine substantial equivalence (see Figure 3). Table 1 compares the attributes of the predicate devices to the Zeltiq CLN1 Dermal Cooling Device. Answers to the relevant questions lead to a determination of substantial equivalence, as follows:

1. DOES THE DEVICE HAVE SAME INDICATION STATEMENTS? ..... YES

Yes. The indications for use for the Zeltiq CLN1 Dermal Cooling Device are the same as those for the predicate cooling / warming devices, the Juniper CLN1 Dermal Cooling Device (K072152) and the MediSeb ElfCare thermal therapy device for both hot and cold applications (K023231).

All three thermotherapy devices are indicated for local management of pain after dermatology procedures, trauma or other surgical procedures. When the optional massage feature of the Zeltiq CLN1 Dermal Cooling Device is employed, the modified device is also substantially equivalent to the Cynosure Triactive Therapeutic Massage System (K030876). Both devices can be used for "temporary improvement in local circulation" and to "temporarily reduce the appearance of cellulite."

2. DOES NEW DEVICE HAVE THE SAME TECHNOLOGICAL CHARACTERISTICS, E.G., DESIGN, MATERIALS, ETC.? ..... YES

Yes. All three thermoelectric thermotherapy devices are designed to cool the skin. All three devices remove heat from small predefined areas of the skin using a non-reactive interface that can maintain (b)(4) (b)(4) All three devices use microprocessor controlled thermoelectric components (b)(4) (b)(4) (b)(4) (b)(4) and all three have a flat electro-thermic electrode patient interface applied directly to the skin. (b)(4) (b)(4)

(b)(4) (b)(4) (b)(4) (b)(4) And, like the Juniper CLN1 Dermal Cooling Device and ElfCare device, the Zeltiq CLN1 Dermal Cooling Device can also heat the skin using a single thermoelectric component. And, finally, like the Juniper CLN1 Dermal Cooling Device and the TriActive Therapeutic Massage System, the Zeltiq CLN1 Dermal Cooling Device can provide powered massage to the targeted treatment area.

3. **ARE THE DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH TO ENSURE EQUIVALENCE? ..... YES**

Yes. The operation of the Zeltiq CLN1 Dermal Cooling Device does not involve a new technological principle. Device operation and application is the same as the predicates, and the application parameters do not differ substantially from other similar devices commercially available in the US.

4. **ARE PERFORMANCE DATA AVAILABLE TO ASSESS EQUIVALENCE? ..... YES**

Yes. Bench testing and software validation demonstrate that the Zeltiq CLN1 Dermal Cooling Device (b)(4) (b)(4) an area of skin. The testing also demonstrated that both the optional vacuum massage feature and the pager performed within specifications.

5. **DOES THE PERFORMANCE DATA DEMONSTRATE EQUIVALENCE? ..... YES**

Yes. Testing confirms that the Zeltiq CLN1 Dermal Cooling Device can be used in an equivalent manner as the predicates.

6. **REASON FOR PREMARKET NOTIFICATION?**

This premarket notification is being submitted in order to obtain clearance to market the Zeltiq CLN1 Dermal Cooling Device with a vacuum applicator and user interface enhancements.

CONCLUSION:

The indications for use for the Zeltiq CLN1 Dermal Cooling Device are the same as the indications for the predicate devices cited in this application. Technological comparisons and bench testing demonstrate that the Zeltiq CLN1 Dermal Cooling Device is functionally equivalent to the predicate devices.

510(K) "SUBSTANTIAL EQUIVALENCE" DECISION MAKING PROCESS FOR THE JUNIPER COOLING DEVICE XTRA

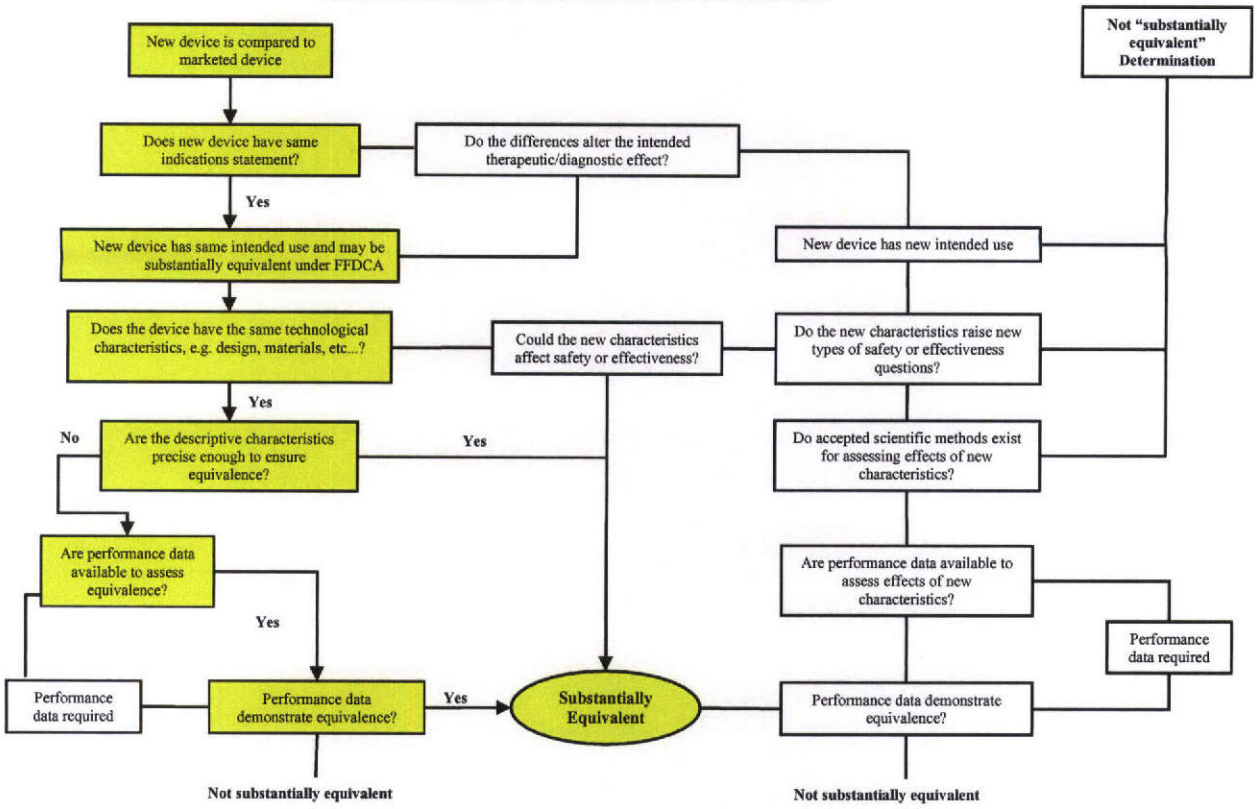
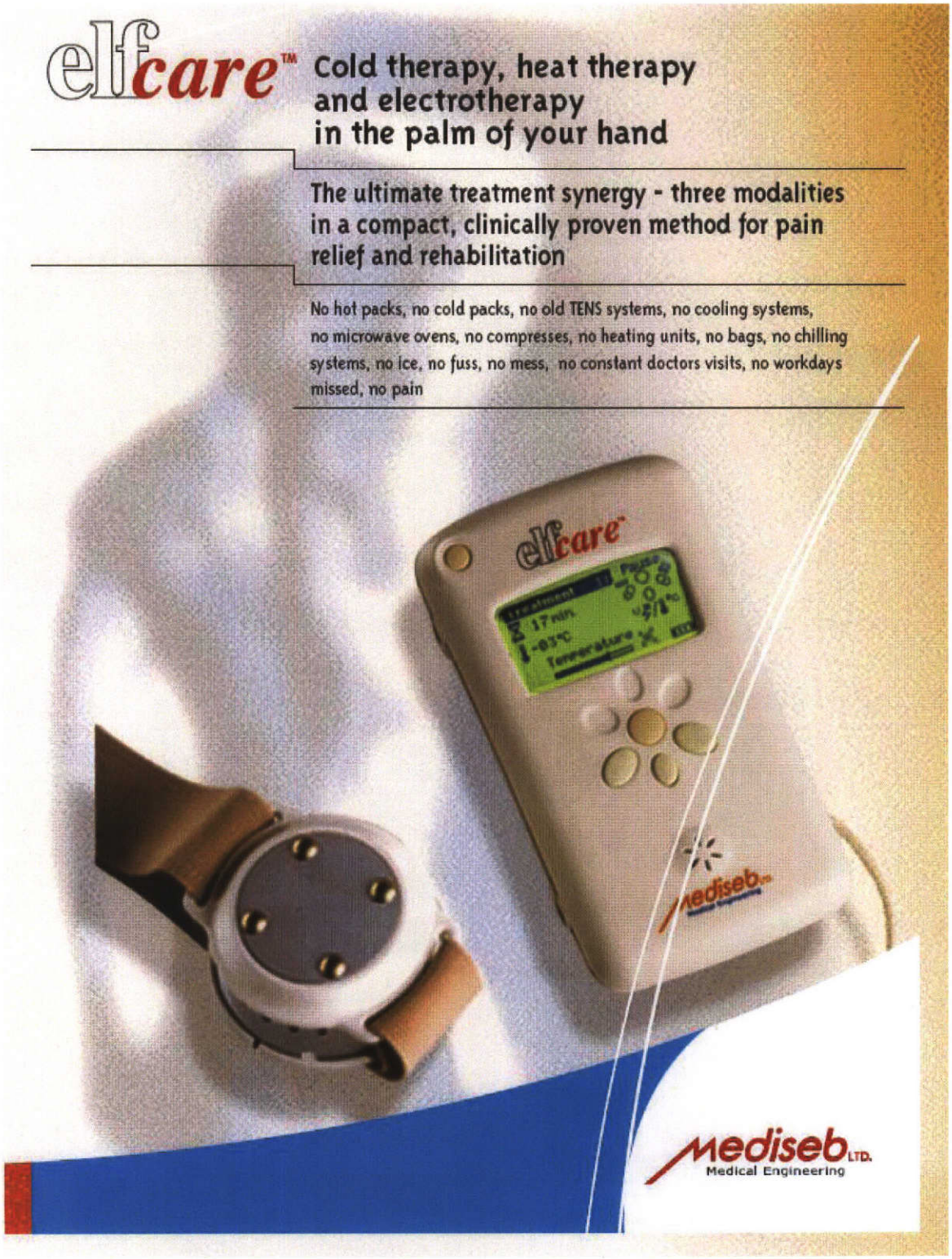
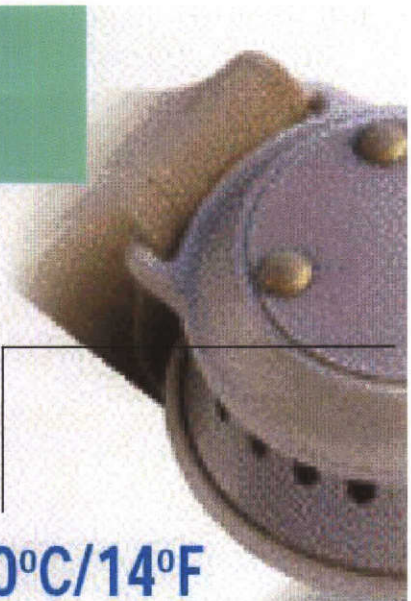


Figure 3. Substantial Equivalence Decision Making Process for the Zeltiq CLN1 Dermal Cooling Device.

ATTACHMENT 14-1. PREDICATE DEVICE INFORMATION – THE ELFCARE DEVICE (K023231)


elfcare™
Cold therapy, heat therapy and electrotherapy in the palm of your hand
The ultimate treatment synergy - three modalities in a compact, clinically proven method for pain relief and rehabilitation
No hot packs, no cold packs, no old TENS systems, no cooling systems, no microwave ovens, no compresses, no heating units, no bags, no chilling systems, no ice, no fuss, no mess, no constant doctors visits, no workdays missed, no pain
elfcare
Mediseb LTD.
Medical Engineering

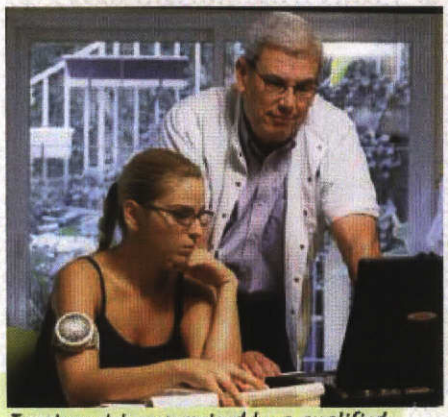
What does ELFcare™ offer me that I can't get from other systems?



- **The only system capable of synergising cold, heat and electrotherapy.**
- **Most effective treatment method currently available** as shown in clinical trials.
- **Close monitoring of the patient's progress.** The unit can be programmed to carry out a complete series of treatments. Elfcare's recall ability will report what treatment was actually carried out, and when.
- **The physician can see more patients in less time** as patients can continue treatment at home.

-10°C/14°F

The electrode becomes icy cold instantaneously as required. Exact temperature calibration - no bags, no mess

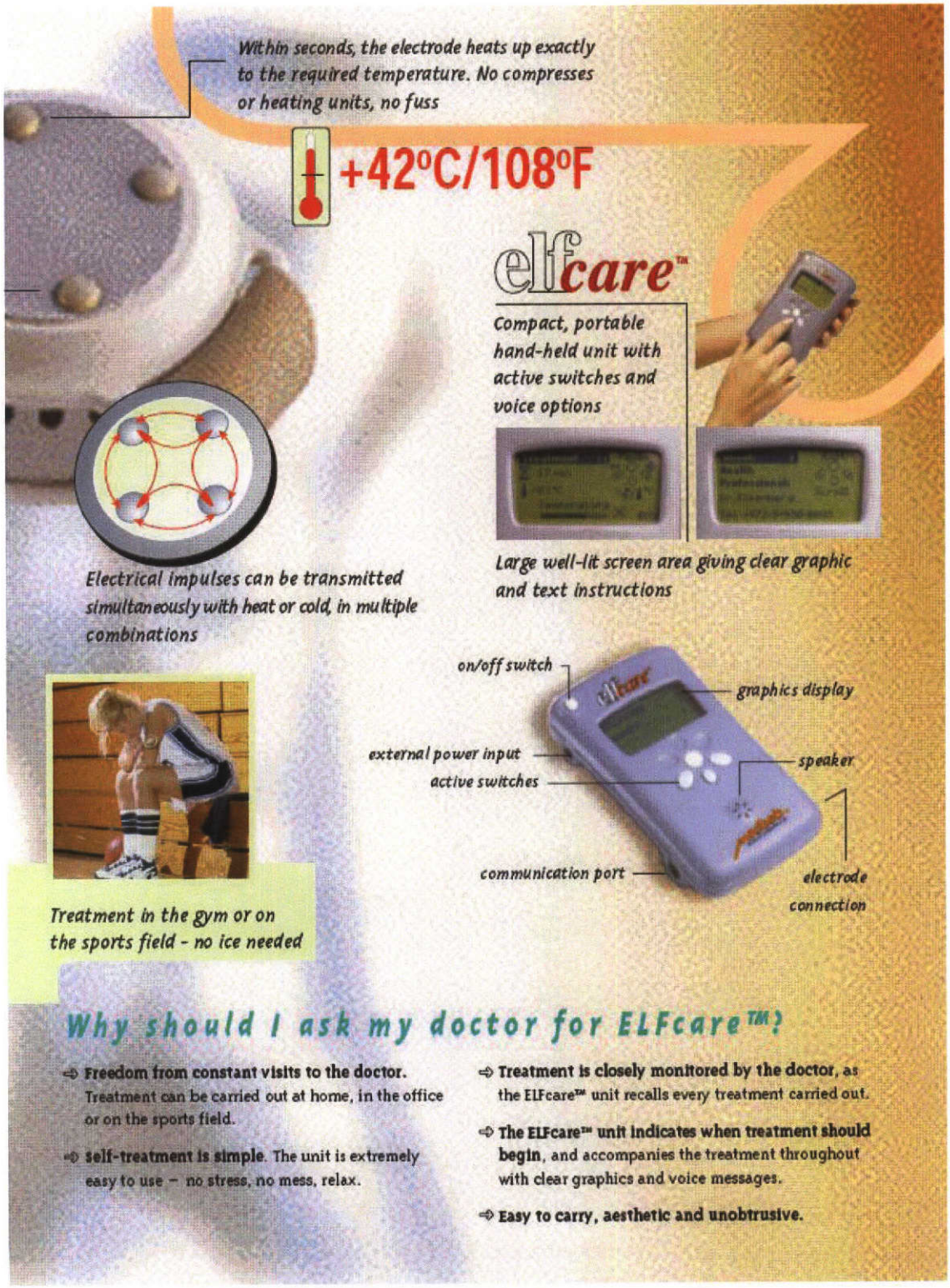


Treatment is supervised by a qualified health professional

Suitable for treatment on all areas of the body

Self-treatment at home is easy. No stress, no mess, relax

- **Fully integrated software package,** including patient file management, algorithm generation and management and a professional package of recommended protocols for use with specific medical conditions.
- **Download treatment protocols from the Internet** directly to the unit via ELFcare's external modem accessory.
- **state-of-the-art patent-pending technology** can synthesize all known algorithms and protocols.


Within seconds, the electrode heats up exactly to the required temperature. No compresses or heating units, no fuss
+42°C/108°F
elfcare™
Compact, portable hand-held unit with active switches and voice options
Electrical impulses can be transmitted simultaneously with heat or cold, in multiple combinations
Large well-lit screen area giving clear graphic and text instructions
on/off switch
graphics display
external power input
active switches
speaker
communication port
electrode connection
Treatment in the gym or on the sports field - no ice needed
Why should I ask my doctor for ELFcare™?
Freedom from constant visits to the doctor. Treatment can be carried out at home, in the office or on the sports field.
Self-treatment is simple. The unit is extremely easy to use – no stress, no mess, relax.
Treatment is closely monitored by the doctor, as the ELFcare™ unit recalls every treatment carried out.
The ELFcare™ unit indicates when treatment should begin, and accompanies the treatment throughout with clear graphics and voice messages.
Easy to carry, aesthetic and unobtrusive.

Features / Model	ELFcare 314A	ELFcare 314B	ELFcare 314C	ELFcare 314D	ELFcare 314E	ELFcare 314F	ELFcare 314G
Electrode Type:							
Electro-Thermal Electrode	●	●	●				
Thermal (Hot/Cold)				●	●		
Rubber Electrode (regular)						●	●
Electrotherapy Waveforms:							
Direct Current - DC (Galvanic)	●	●	●			●	●
Alternating Current - AC	●	●	●			●	●
Interferential Current (IFC)	●	●	●			●	●
Pulsed Current (PC)	●	●	●			●	●
Phase/Pulse Modulation	●	●	●			●	●
Preset Procedures Capability:							
16 Programs							●
32 Programs					●	●	
64 Programs			●	●			
128 Programs		●					
256 Programs	●						
Communication:							
Download programs and system updates	●	●	●	●	●	●	●
Upload log file history	●	●	●			●	●
Physiotherapy Software Modules (on PC):							
Physiotherapy Guide (SPG)	●	●	●				
Treatment Waveform Builder (STWB)	●	●	●				

Technical Data:

Current Stimulation	
Waveforms:	DC (galvanic), Faradic current, Diadynamic current (DF, MF, RS, CP, LP, DF/CP, DF/LP), I.F. current, Medium Freq., Russian stim, Pulsed current (Rectangular, Triangular, Exponential), TENS, Micro current, High voltage.
Mode:	Constant Current/Constant Voltage.
Intensity:	0 - 90mA at 500Ω.
Pulse Width:	5µS - 1000mS.
Pulse Rate:	1Hz - 10KHz.
Temperature Stimulation	
Range:	-10°C - 42°C / 14°F - 108°F.
Variability:	3 minute (min to max without load).
Accuracy:	±1°C / ±1.8°F (stabilized on load).
General	
Display:	Graphic LCD (STN) 128 x 64 dots including Back-Light.
User guidance:	On screen.
Programming capabilities:	Up to 256 programs.
Real Time Clock:	Hour/Day/Month/Year.
Communication:	RS-232 port.
Control system:	Advanced digitally controlled computerized system.
Treatment time:	1 - 60 minutes.
Dimensions (L x W x H):	155mm x 91mm x 51mm / 6.1" x 3.6" x 2".
Weight:	Device: 210g / 7.4 ounces (without batteries) Electrode: 180g / 6.3 ounces.
Supply voltage:	Internal: NiCd/NiMH 4.8V/1800mAH Battery External: Power Supply (Input: 110VAC-240VAC, output: 5.5VDC/3A ±5%).

Standard Accessories	
TE-314A:	Electro-Thermal Electrode for ELFcare™ 314A,B,C models.
TE-314:	Electro-Thermal Electrode for ELFcare™ 314D,E models.
RE-314:	Rubber Electrode for ELFcare™ 314F,G models.
AD-314:	Rubber Electrode Adaptor for ELFcare™ 314F,G models.
Optional Accessories	
CB-314:	Carrying Bag.
PS-314:	Power Supply Input: 110VAC - 240VAC, output: 5.5VDC / 3A ±5%.
TR-115:	AC Adaptor, Input: 110VAC - 120VAC, output: 6VDC / 3A ±5% (only for charging purposes).
TR-230:	AC Adaptor, Input: 220VAC - 240VAC, output: 6VDC / 3A ±5% (only for charging purposes).
RE-314:	Rubber Electrode Adaptor.

Special features:

- Recall ability: memory is retained by the unit even in the case of battery failure or replacement.
- Built-in safety features monitoring temperature and electrical signals ensure that the treatment is kept within the limits of the specified protocol.
- Voice messages inform the patient when to start and stop treatment.
- AUTO START, AUTO STOP and timer functions.
- Locking system prevents unauthorized changes to treatment parameters.
- System malfunction is prevented by self-diagnostic and unit problem detection software, constant current/voltage output and zero start of output.
- The advanced computerized control system makes upgrades of new programs or display effects easy to carry out.

Design: Photography: Amir

Mediseb LTD.
Medical Engineering
Mediseb Ltd. 6 Galgaley Ha'plada st.,
P.O.B. 12678, Herzlia, 46733, Israel
Tel: +972-9-950-0885; Fax: +972-9-950-0886
E-mail: segev@mediseb.com
http://www.mediseb.com

ATTACHMENT 14-2. PREDICATE DEVICE INFORMATION – CYNOSURE TRIACTIVE THERAPEUTIC MASSAGER (K030876)

TRI·ACTIVE
Beauty Under a New Light

PRODUCT SPECIFICATIONS

Type of laser	Semi-conductor
Wavelength	808 nm
Power	6x1 W (max) (Meet class 4 class I Laser)
Variable aspiration	Frequency 0.1 ÷ 5 Hz - Duty cycle10 ÷ 90%
Power supply	110 Vac - 3 A (max) - 50/60 Hz
Dimensions	47" (120 cm) (H) - 19" (48 cm) (W) - 24" (60 cm) (D)
Weight	88 lbs (40 kg)

MAIN APPLICATIONS

- MINIMIZE CELLULITE
- PRE AND POST-LIPOSUCTION PROCEDURES
- FACIAL SMOOTHING OF CELLULITE
- BODY SMOOTHING OF CELLULITE
- ENHANCES MICROCIRCULATION
- THERAPEUTIC MASSAGE

CE 0459

www.cynosurelaser.com
www.laserfacial.biz

Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, MA 01824 USA
Tel: 978-256-4200
Toll-Free: 800-886-2966
Fax: 978-256-6556

OBJECTIVE:
a perfect figure.

Tri•Active is the result of DEKA 's new technology based on the combination of three different methods capable of restoring a normal balance to your skin.
This treatment is designed to dramatically reduce the appearance of cellulite through the combined action of a localized cooling system, rhythmic massage and deep laser stimulation.

SMOOTHING AND TONING

TIGHTENING

MODELLING

RESULT:
a body always in shape.

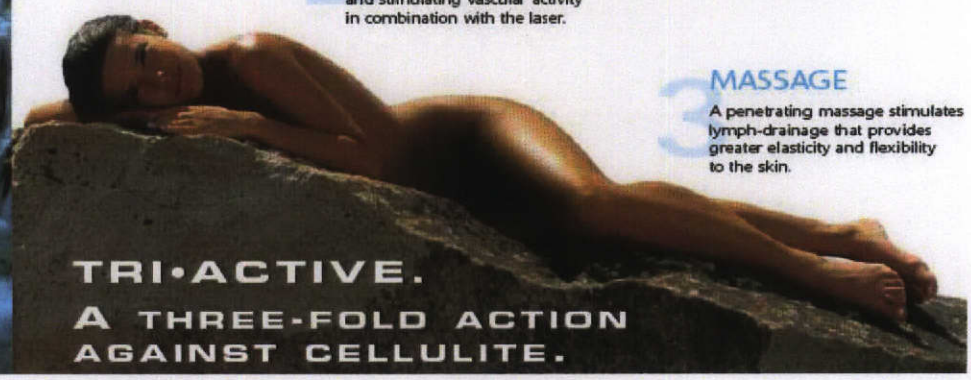
Cellulite and Dermodynamic method.

The deep massaging and stimulating action on the subcutaneous tissue allow toxin elimination and tissue oxygenation, thus creating a smoother appearance of the skin.

1 STIMULATION
The laser action stimulates blood micro circulation within the veins and arteries while also increasing lymphatic capacity.

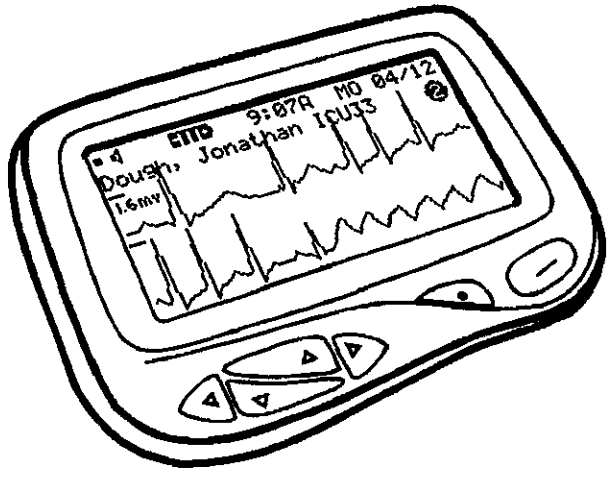
2 COOLING
Cryotherapy aids in cellulite reduction by reducing oedema and stimulating vascular activity in combination with the laser.

3 MASSAGE
A penetrating massage stimulates lymph-drainage that provides greater elasticity and flexibility to the skin.



TRI•ACTIVE.
A THREE-FOLD ACTION AGAINST CELLULITE.

ATTACHMENT 14-3. PREDICATE DEVICE INFORMATION – ULTRAVIEW CLINICAL MESSENGER (K992749)



Ultraview™ Clinical Messenger

Wireless Alarm & Waveform Messaging System

91841

- Alarm notification to pager in 4 to 8 seconds
- Displays up to 12 seconds of the alarmed waveform for any monitored parameter
- Receives broadcasts of vital signs at user-specified intervals to aid in remote monitoring of acute patients
- Waveforms and alarms from standalone devices connected via Flexport® system interface
- Second Messenger™ feature helps ensure quick response
- Operates in the protected 929-931 MHz paging band
- High-resolution LCD display – not for diagnosis
- Stores alarm and waveform information for later retrieval
- Easy-to-use Windows-based administration module
- Compact size

SPECIFICATIONS

The Ultraview Clinical Messenger Wireless Alarm and Waveform Messaging System provides caregivers mobility with alarm notification. Typically, notification occurs within 4 to 8 seconds after an alarm event (for telemetry and hardwired patients). The system provides an audio and/or vibrating alert along with a series of displays that show patient identification, alarm parameters, and up to a 12-second waveform snapshot. The Ultraview Second Messenger feature allows alarms to escalate to alternate caregivers if alarms are not addressed in a specific time period. Users may also schedule patient status updates for dispatch on a repeating basis if desired.

The administration module enables convenient assignment of patients to caregivers from any location on the network, including WinDNA®-enabled Ultraview 1700 and Universal Clinical Workstations (UCW®).

Intended Use — The Ultraview Clinical Messenger Wireless Alarm and Waveform Messaging System is designed to interface with the Spacelabs Medical monitoring network to provide a secondary means of notification and display of patient alarm information to mobile health care providers. The device is indicated for use in real-time monitoring of routine patient status and alarm events. The messaging system

Page 1 of 2

Ultraview Clinical Messenger Wireless Alarm & Waveform Messaging System 91841

Spacelabs Medical, Inc.
15220 N.E. 40th Street
P.O. Box 97013
Redmond, WA 98073-9713
Telephone: (425) 882-3700
Fax: (425) 885-4877
Telex: 4740085 SPL UI

www.spacelabs.com

061-1079-00 Rev. C 05/2001

SPECIFICATIONS

is intended to serve as a parallel, redundant mechanism to inform the clinical staff of patient events.

The Clinical Messenger system serves as a secondary alarm in any hospital environment currently using or intending to use a Spacelabs patient-monitoring network. The Clinical Messenger system supplements the primary patient-monitoring system by providing a forwarding mechanism for announcing and displaying patient alarm events and the critical information associated with the events – including parameter values and waveforms. The pager provides an audio or vibrating alert along with a series of displays showing patient identification, alarm parameters and waveform snapshot.

The Ultraview Clinical Messenger Wireless Alarm and Waveform Messaging System is a secondary alarm. It does not replace the primary alarm function on the monitor.

HARDWARE REQUIREMENTS:

Pagers and Transmitter System —

Motorola CP1250 Advanced Information Services World Messaging Pagers.

The pager transmitter system must be Flex-Binary protocol capable. Other requirements for the pager transmitter and antenna are site-specific. A site survey is performed to determine coverage area and system requirements.

Clinical Messenger System —

- Clinical Messenger server
- Clinical Messenger Flex Encoder server
- Flex-Binary paging transmitter
- Monitor
- Keyboard
- Mouse
- Switch box
- Network and serial connections

All hardware for use with the Ultraview Clinical Messenger Wireless Alarm and Waveform Messaging System must meet all federal and international standards pertaining to electromagnetic emissions and interference.

15. PROPOSED LABELING

The following sections contain:

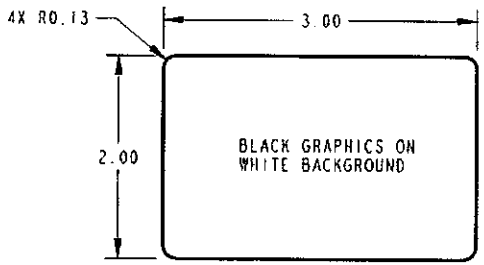
- The proposed labeling and instructions for use for the Zeltiq CLN1 Dermal Cooling Device (Attachment 15-1 and Attachment 15-2, respectively);
- The proposed labeling and instructions for use for the Zeltiq Vacuum Applicator Single Patient Use Sleeve Directions for Use – (Attachment 155-3 and Attachment 155-4, respectively)

ATTACHMENT 15-1. PROPOSED LABELING FOR THE ZELTIC CLN1 DERMALCOOLING DEVICE

NOTES:
1. APPLICABLE STANDARDS/SPECIFICATIONS:
   ASME/ANSI Y14.5M-1994, DIMENSIONS AND TOLERANCES
   ASME/ANSI Y14.5M-1999, ABBREVIATIONS
2. ALL DIMENSIONS ARE IN INCHES.
3. DRAWING CREATED FROM 3D CAD MODEL
4. DEBURR AND BREAK SHARP EDGES .010 MAX.
5. MATERIAL:.002" 3M 7331 T/C 200 WHITE MYLAR W/.001" PERMANENT ACRYLIC ADHESIVE(#300)
6. FINISH: LAMINATE WITH CLEAR .001" MATTE TYPEABLE/WRITEABLE MYLAR
7. SOLID DOT INDICATES KEY INSPECTION DIMENSION OR TOLERANCE.
8. PART TO BE CLEAN AND FREE OF CONTAMINANTS.
9. PACKAGE PARTS TO PREVENT DAMAGE DURING SHIPPING AND HANDLING.
   PACKAGE TO BE IDENTIFIED WITH PART NO. AND REVISION LEVEL.
10. VENDOR TO SUPPLY MATERIAL CERTIFICATION WITH EACH SHIPMENT.

REVISIONS

REV	DESCRIPTION	DATE	APPROVED
B	Released Co-00257	05/22/07	



ORIGINAL

GENERAL DIMENSIONAL TOLERANCES		
.X±	.XX±	.XXX±
.1	.02	.005
HOLES±	FRAC.±	ANG.±
---	1/64	1°

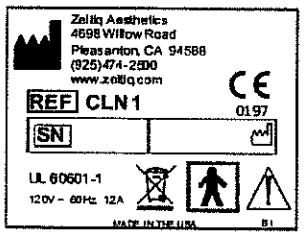
THIRD ANGLE PROJECTION

Juniper Medical
4698 Willow Road, Suite 100
Pleasanton, CA 94588

TITLE: LABEL, INSTRUMENT CLNI

DWG NAME:	EN-10599
PTC MDL VER:	B.1
DRAWN BY	
CHECKED	
DWG NO:	EN-10599
REV	B
B	SCALE: 1/1
SHEET	1 OF 2

278



ARTWORK NOT TO SCALE

Juniper Medical 4698 Willow Road, Suite 100 Pleasanton, CA 94588	This document contains or represents confidential and proprietary information of Juniper Medical, Inc., and may not be copied, disclosed, or used, in whole or in part, without the prior consent of Juniper Medical, Inc.	
DRAWN BY:	DWG NO. EN-10599	REV B
	B SCALE:	SHEET 2 OF 2

ATTACHMENT 15-2. PROPOSED INSTRUCTIONS FOR USE FOR THE ZELTIQ CLN1 DERMAL COOLING DEVICE

Zeltiq CLN1 Dermal Cooling Device
Directions for Use

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Zeltiq Aesthetics, Inc.
4698 Willow Road
Pleasanton, CA 94588
(925) 474-2500
www.zeltiq.com

Authorized Representative
Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

Pages 83 through 100 redacted for the following reasons:
- -
User Manual, not distributed publicly, b4

ATTACHMENT 15-3. PROPOSED LABELING FOR THE ZELTIQ VACUUM APPLICATOR SINGLE PATIENT USE SLEEVE

Zeltiq

②

Manufactured at: 4698 Willow Road
Pleasanton, CA 94588
www.zeltiq.com

(b)(4)

(b)(4)

ATTACHMENT 15-4. PROPOSED DIRECTIONS FOR USE FOR THE ZELTIQ VACCUM APPLICATOR SINGLE PATIENT USE SLEEVE

Zeltiq Aesthetics Vacuum Applicator Single Patient Use Sleeve Directions for Use

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Zeltiq Aesthetics, Inc.
4698 Willow Road
Pleasanton, CA 94588

Authorized Representative:
Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
Phone: +31.70.345.8570
FAX: +31.70.346.7299

Pages 105 through 111 redacted for the following reasons:
- -
b4

16. STERILIZATION & SHELF LIFE

The Zeltiq CLN1 Dermal Cooling Device, including the applicators and disposable sleeves, are not sold sterile. The shelf life for the disposable sleeve is 6 months.

17. BIOCOMPATIBILITY

17.1. ZELTIQ CLN1 DERMAL COOLING DEVICE

The only new patient contacting materials introduced in the design upgrade to the Zeltiq CLN1 Dermal Cooling Device are the (b)(4) (b)(4) (b)(4) (b)(4) used with the coupling gel at the interface between the applicator and the skin. Both of these materials have a long history of use in medical devices and, therefore, full biocompatibility testing was not repeated by Zeltiq.

(b)(4) (b)(4) (b)(4) (b)(4) The material has a long history of use not only for short-term external applications such as the intended use of the applicator sleeve but also for permanent implants. Therefore, only a cytotoxicity test was performed on a (b)(4) (b)(4) the applicator sleeve. Using the ISO Elution Method (ISO 10993), the sample showed no evidence of any cell lysis or toxicity; see Attachment 17-1 for a copy of the test report.

(b)(4) (b)(4) (b)(4) (b)(4)

ATTACHMENT 17-1 TR-044 BIOCOMPATIBILITY TESTING OF LDPE FROM BLOOMER PLASTICS

Biocompatability testing of (b)(4) (b)(4)
(b)(4) (b)(4) V2 SPUS
TR-044

(b)(4) (b)(4)
20-Dec-07

(b)(4)
(b)(4)

1. Summary

(b)(4)

(b)(4)

2. Purpose

(b)(4)

(b)(4)

3. References

(b)(4)

(b)(4)

4. Background

(b)(4)

(b)(4)

5. Methods

(b)(4)

(b)(4)

6. Results

(b)(4)

(b)(4)

7. Conclusions

(b)(4)

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REPORT

TEST FACILITY:

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SPONSOR:

(b)(4)
(b)(4)
Zeltiq Aesthetics
4698 Willow RoadSuite 100
Pleasanton , CA 94588

CONFIDENTIAL

STUDY TITLE:

Cytotoxicity Study Using the ISO Elution Method
(1X MEM Extract)

TEST ARTICLE:

(b)(4)
(b)(4)

IDENTIFICATION NO.:

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1. Introduction

Purpose
The test article identified below was extracted, and the extract was subjected to an *in vitro* cytotoxicity study for biocompatibility based on the requirements of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity: *in vitro* Methods. The test was performed to determine whether leachables extracted from the material would cause cytotoxicity.

Dates
The test article was received on August 20, 2007. The cells were first exposed to the extract August 23, 2007, and the observations were concluded on August 25, 2007.

2. Materials

The test article provided by the sponsor was identified and handled as follows:

Test Article:	Item 015-10-B
Identification No.:	Code Item 015-10-B
Storage Conditions:	Room Temperature
Extraction Vehicle:	Single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (1X MEM)
Test Article Preparation:	Based on the USP ratio of 120 cm^2:20 ml, a 60 cm^2 portion of the test article was covered with 10 ml of 1X MEM. A single preparation was extracted with agitation at 37°C for 24 hours.
Negative Control Preparation:	(b)(4) (b)(4) (b)(4) The preparation was subjected to the extraction conditions previously described for the test article.
Reagent Control Preparation:	A single aliquot of 1X MEM without test material was subjected to the same extraction conditions as described for the test article.
Positive Control Preparation:	The current NAMSA positive control, (b)(4) (b)(4) was used. Based on the USP ratio of 60 cm^2:20 ml, a single 29.6 cm^2 portion of the control material was covered with 9.9 ml of 1X MEM and extracted with agitation at 37°C for 24 hours.
Condition of Extracts:	Test: Clear Reagent Control: Clear Negative Control: Clear Positive Control: Clear

3. Test System

Test System Management
L-929, mouse fibroblast cells, (ATCC CCL 1, NCTC Clone 929, of strain L, or equivalent source) were propagated and maintained in open wells containing single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (1X MEM) in a gaseous environment of 5% carbon dioxide (CO_2). For this study, 10 cm^2 wells were seeded, labeled with passage number and date, and incubated at 37°C in 5% CO_2 to obtain sub-confluent monolayers of cells prior to use. Aseptic procedures were used in the handling of the cell cultures following approved NAMSA Standard Operating Procedures.

4. Methods

Triplicate culture wells were selected which contained a sub-confluent cell monolayer. The growth medium contained in triplicate cultures was replaced with 2 ml of the test extract. Similarly, triplicate cultures were replaced with 2 ml of the reagent

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5. Results

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6. Conclusion

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7. Records

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8. References

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Appendix 1 - Reactivity Grades For Elution Testing

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18. SOFTWARE

The Zeltiq CLN1 Dermal Cooling Device software has two components: the Control Unit and the Applicator.

The Control Unit software provides the user interface to select a treatment profile and apply treatment. It controls the chiller (housed within the control unit) and the Applicator. The Control Unit (b)(4) (b)(4) (b)(4) (b)(4) A data logging service is also provided by the Control Unit.

The Applicator software responds to commands from the Control Unit (b)(4) (b)(4) (b)(4) (b)(4) Communication must be maintained between the Control Unit and Applicator for treatment to start and continue.

Key changes to the Zeltiq CLN1 Dermal Cooling Device software from that of the predicate includes:

- (b)(4)
- (b)(4) (b)(4) and
- Use of an optional pager that notifies the user of device status during treatment such as when the treatment is complete or if a system error occurs.

A full software validation was conducted to assure that these changes were properly implemented. A copy of the validation report can be found in Attachment 16-1.

18.1. LEVEL OF CONCERN

The level of concern for the Zeltiq CLN1 Dermal Cooling Device is moderate. Operation of the device via the associated software directly affects the patient and/or operator such that failures or latent design flaws could result in a non-serious (minor-moderate) injury to the patient and/or operator.

Documentation provided in support of the software modifications incorporated into the Zeltiq CLN1 Dermal Cooling Device is in compliance with the Guidance for the Content of Premarket Submission for Software Contained in Medical Devices (May 11, 2005) for a moderate level of concern determination. This documentation is described in the following sections with complete documents provided, when required, as appendices.

18.2. SOFTWARE DESCRIPTION

The software is described in DR10051, Software Design Description, included as Attachment 18-1. The major processors in the Zeltiq CLN1 Dermal Cooling Device include:

- (b)(4) (b)(4)
- (b)(4) (b)(4) interfaces between the (b)(4) and the rest of the system hardware

The (b)(4) and (b)(4) comprise the Control Unit.

- (b)(4) (b)(4) – control overall applicator functions
- (b)(4) (b)(4) – (b)(4) control TEC heating and cooling

The (b)(4) (b)(4) and (b)(4) (b)(4) comprise the Applicator software.

18.3. DEVICE HAZARD ANALYSIS

The hazard analysis consists of both a System Hazard Analysis (SHA), DR10320, included as Attachment 18.2, and a Failure Modes Effects Analysis (FMEA), DR10622, included as Attachment 18.3. All identified risks have been mitigated to a level that is acceptable.

18.4. SOFTWARE REQUIREMENTS SPECIFICATION

See Zeltiq document DR10020, CLN1 Software Requirements Specification, Attachment 18-4.

18.5. ARCHITECTURE DESIGN

The software architecture design is included in Zeltiq document DR10051, CLN1 Software Design Description, as Figure 1. This document is included in Attachment 18-1

18.6. TRACEABILITY ANALYSIS

The software traceability analysis is discussed in Zeltiq document TR-050, CLN1 SW Release 08 Verification Test Report. Software requirements that trace to code resulted in a code inspection to ensure that the requirements were met. The code inspection is tabulated in TR-050, included in Attachment 18-5.

18.7. SOFTWARE DEVELOPMENT ENVIRONMENT

The software development environment is described in Section 6.4 of Zeltiq document DR10013, CLN1 Software Development Plan. Document DR10013 is included in Attachment 18-7.

18.8. SOFTWARE VERIFICATION AND VALIDATION (V&V)

The software V&V test plan is described in Zeltiq document DR10690, CLN1 Software Verification Procedure Specification. This document is included as Attachment 18-6. The results of the V&V are included as Section 7 in Zeltiq document TR-050, CLN1 SW Release 08 Verification Test Report. This document is included in Attachment 18-5.

18.9. REVISION LEVEL HISTORY LOG

The revision level history log is described in Table 3 below.

Table 3. Software Revision History Log.

Software Release	CO	Effective Date	V&V	Key Additions / Changes
05	00118	11 July 2007	TR-10710	Initial release
06	00134	14 Aug 2007	TR-033	Add Vacuum applicator feature
07	00171	02 Oct 2007	TR-040	(b)(4) (b)(4)
08	00242	11 Jan2008	TR-050	Current release described in this section

18.10. UNRESOLVED REMAINING SOFTWARE ANOMALIES

There are no unresolved anomalies that represent any patient or operator hazards. The remaining unresolved software anomalies, caller deferred Software Correction Request (SCRs), are listed in Section 8 of TR-050, CLN1 SW Release 08 Verification Test Report, included in Attachment 18-5.

ATTACHMENT 18-1. SOFTWARE VALIDATION : DR10051, CLN1 SOFTWARE DESIGN DESCRIPTION

Author / Revised by: (b)(4) (b)(4)	Approved By:	Date: December 19, 2007
Project: CLN1		
Title: CLN1 Description, Software Design		

Revision	CO #	Approval Date	Effective Date	Description
02	CO-00125	7/25/07	7/25/07	Update to reflect current design.
A	CO-00215	12/19/07	11/20/07	Rev A Release

Revision History

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Figure 1 (b)(4) **Software Architecture Overview**

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7.14 Block Diagram of (b)(4)

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7.15 Block Diagram of (b)(4)

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ATTACHMENT 18-2. DR10320, SYSTEM HAZARD ANALYSIS (SHA)

DR-10320
CLN 1 System Hazard Analysis

Hazard	Severity	Potential Cause	Current Design Mitigations	Notes and justification	Probability	Risk	Additional Mitigations	Probability	Risk
(b)(4)									

349

DR-10320
CLN 1 System Hazard Analysis

Hazard	Severity	Potential Cause	Current Design Mitigations	Notes and justification	Probability	Risk	Additional Mitigations	Probability	Risk

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DR-10320
CLN 1 System Hazard Analysis

Hazard	Severity	Potential Cause	Current Design Mitigations	Notes and justification	Probability	Risk	Additional Mitigations	Probability	Risk
(b)(4)									

(b)(4)

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DR-10320
CLN 1 System Hazard Analysis

Hazard	Severity	Potential Cause	Current Design Mitigations	Notes and justification	Probability	Risk	Additional Mitigations	Probability	Risk

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ATTACHMENT 18-3. DR10622, FAILURE MODES AND EFFECTS ANALYSIS

CLN 1 Design FMEA

Device: Juniper CLN1 Dermal Skin Cooling Device

Analysis Record

(b)(4)

(b)(4)

354

CLN 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	D/U	Sev erit y	Current Design Mitigations	Notes and justification	Probab ility	Risk	Mitigation	Prob-ability	Risk	Detect-ability	Risk with Detect-ability
(b)(4)														

(b)(4)

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CLN 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	D/U	Sev erit y	Current Design Mitigations	Notes and justification	Probab ility	Risk	Mitigation	Prob-ability	Risk	Detect-ability	Risk with Detect-ability
(b)(4)														

(b)(4)

356

(b)(4)

Module	Failure	Potential Cause (origin)	Hazard	D/U	Severity	Current Design Mitigations	Notes and justification	Probability	Risk	Mitigation	Prob-ability	Risk	Detect-ability	Risk with Detect-ability

(b)(4)

377

Module	Failure	Potential Cause (origin)	Hazard	D/U	Severity	Current Design Mitigations	Notes and justification	Probability	Risk	Mitigation	Prob-ability	Risk	Detect-ability	Risk with Detect-ability
(b)(4)														

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313

CLN 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	D/U	Severity	Current Design Mitigations	Notes and justification	Probability	Risk	Mitigation	Prob-ability	Risk	Detect-ability	Risk with Detect-ability

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CLN 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	D/U	Severity	Current Design Mitigations	Notes and justification	Probability	Risk	Mitigation	Prob-ability	Risk	Detect-ability	Risk with Detect-ability

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CLN 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	D/U	Severity	Current Design Mitigations	Notes and justification	Probability	Risk	Mitigation	Prob-ability	Risk	Detect-ability	Risk with Detect-ability

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CLN 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	D/U	Sev erit y	Current Design Mitigations	Notes and justification	Probab ility	Risk	Mitigation	Prob-ability	Risk	Detect-ability	Risk with Detect-ability
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CLN 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	D/U	Severity	Current Design Mitigations	Notes and justification	Probability	Risk	Mitigation	Prob-ability	Risk	Detect-ability	Risk with Detect-ability
(b)(4)														

(b)(4)

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Module	Failure	Potential Cause (origin)	Hazard	D/U	Severity	Current Design Mitigations	Notes and justification	Probability	Risk	Mitigation	Prob-ability	Risk	Detect-ability	Risk with Detect-ability

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CLN 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	D/U	Severity	Current Design Mitigations	Notes and justification	Probability	Risk	Mitigation	Prob-ability	Risk	Detect-ability	Risk with Detect-ability
(b)(4)														

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CLN 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	D/U	Severity	Current Design Mitigations	Notes and justification	Probability	Risk	Mitigation	Prob-ability	Risk	Detect-ability	Risk with Detect-ability
(b)(4)														

(b)(4)

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CLN 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	D/U	Sev erit y	Current Design Mitigations	Notes and justification	Probab ility	Risk	Mitigation	Prob-ability	Risk	Detect-ability	Risk with Detect-ability
(b)(4)														

(b)(4)

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CLN 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	D/U	Severity	Current Design Mitigations	Notes and justification	Probability	Risk	Mitigation	Prob-ability	Risk	Detect-ability	Risk with Detect-ability
(b)(4)														

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CLN 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	D/U	Severity	Current Design Mitigations	Notes and justification	Probability	Risk	Mitigation	Prob-ability	Risk	Detect-ability	Risk with Detect-ability
(b)(4)														

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ATTACHMENT 18-4. DR10020, SOFTWARE REQUIREMENTS SPECIFICATION

Author / Revised by: (b)(4) (b)(4)	Approved By:	Date: 2 Jan 2008
Project: CLN1		
Title: CLN1 Specification, Software Requirements		

Revision	CO #	Approval Date	Effective Date	
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Revision History

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ATTACHMENT 18-5. TR-050, CLN1 SOFTWARE RELEASE 08 VERIFICATION TEST REPORT

CLN1 SW Release 08 Verification Summary Report
TR-050

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11 January 2008

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ATTACHMENT 18-6. DR10690, CLN1 SOFTWARE VERIFCATION PROCEDURE SPECIFICATION

Author / Revised by: (b)(4)	Approved By:	Date: 09 Jan 2008
Project: CLN1		
Title: CLN1 Specification, SW Verification Procedure		

Revision	CO #	Approval Date	Effective Date	Description
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Revision History

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ATTACHMENT 18-7. CLN1 SOFTWARE DEVELOPMENT PLAN

Author / Revised by: (b)(4)	Approved By:	Date: July 17, 2007
Project: CLN 1		
Title: CLN1 Software Development Plan		

(b)(4)

(b)(4)

Table of Contents

1 Purpose

(b)(4)

(b)(4)

(b)(4)

2 Scope

(b)(4)

(b)(4)

3 Reference Documents

1. (b)(4)
2.
3.

(b)(4)

4 Definitions

5 Responsibilities

(b)(4)

(b)(4)

6 Procedure

(b)(4)

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19. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

(b)(4)

(b)(4)

20. PERFORMANCE TESTING - BENCH

(b)(4)

(b)(4)

ATTACHMENT 20-1. (b)(4) APPLICATOR VERIFICATION REPORT

Report, Verification, (b)(4) Applicator
TR-035

(b)(4)
(b)(4)

13-Sep-07

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1. Summary

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2. Purpose

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3. References

(b)(4)

1.
2.
3.
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6.

(b)(4)

4. Methods

(b)(4) (b)(4)

5. Results

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6. Conclusions

(b)(4)

(b)(4)

Juniper Medical, Inc.	**Component Specification Sheet**	
Part Number: (b)(4) (b)(4)	(b)(4) (b)(4)	
Approval Signature:	Release Date: June 27, 2007	Revision: A

Vendor	Vendor ID	Vendor's Part Number
1 (b)(4) (b)(4)		(b)(4) (b)(4)
2.		
3.		

Manufacturer *	Manufacturer's Part Number

*Supply Manufacturer information if available.

Additional Data or Specific Information:

(b)(4) (b)(4)

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CLN1 System Verification Protocol Results

(b)(4)

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ATTACHMENT 20-2. TR-031(b)(4) VACUUM DISPOSABLE SLEEVE VERIFICATION TEST REPORT

Verification Test Report

(b)(4) Vacuum Applicator Disposable
TR-031

Zeltiq Aesthetics, Inc.
11-Sep-07

(b)(4)

(b)(4)

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1. Summary

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2. Purpose

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3. References

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4. Background

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5. Methods

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6. Results

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(b)(4)

7. Conclusions

(b)(4)

(b)(4)

21. PERFORMANCE TESTING - ANIMAL

(b)(4) (b)(4)

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Long Chen

Subject: 510(k) Number K080118/S1

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X

Rev. 7/2/07

5

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number	Class*	Product Code
21 CFR 878.4810	II	GEX, GEH

(*If unclassified, see 510(k) Staff)

Additional Product Codes: ILO, ISA

Review: (Branch Chief) GSDB (Branch Code) 5/1/08 (Date)

Final Review: for (Division Director) 5/2/08 (Date)

6

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K080118/S2

Date: April 30, 2008
To: The Record
From: Long Chen, Ph.D. Chemical Engineer

Office: ODE
Division: DGRND/GSDB

510(k) Holder: Zeltiq Aesthetics, Pleasanton, CA
Device Name: **Zeltiq Aesthetics CLN1 Dermal Cooling Device**
Contact: Donald V Johnson, VP Operations, Regulatory, & Quality Affairs
Phone: (b)(4) (b)(4)
Fax: (b)(4) (b)(4)
Email: (b)(4) (b)(4)

I. Purpose

The 510(k) holder would like to introduce the subject modified Zeltiq Aesthetics CLN1 Dermal Cooling Device into interstate commerce.

This device has been previously cleared as Juniper CLN1 Dermal Cooling Device (K072152). In this submission, the sponsor has made an upgrade to the accessories and software. In addition, the sponsor noted that Juniper Medical, Inc. has changed the company name to Zeltiq Aesthetics, Inc. as of July 31, 2007.

This device is for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. It can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. In addition, the massage function can be used for the relief of minor muscle aches, pain and spasm and for the improvement in local circulation and temporary reduction in the appearance of cellulite. According to the sponsor, the upgrade was implemented

- to include a vacuum applicator that provides pulsatile message;
- to use a (b)(4) (b)(4), (b)(5) with the Zeltiq gel as the interface between the applicator sleeve and the skin;
- to modify the hardware and software to include a transmitter system that supports a pager.

The sponsor indicated that the treatment parameters will be the same as the predicate, Juniper CLN1 Dermal Cooling Device (K072152). This includes the treatment temperature (b)(4) (b)(4), (b)(5) the maximum application time from (b)(4) (b)(4), (b)(5) and the maximum applicator interface surface area of (b)(4) (b)(4), (b)(5) The range of the vacuum pressure will be from (b)(4) (b)(4), (b)(5) The verification test for the vacuum applicator was conducted and the results are also provided.

(b)(4)

(b)(4)

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(b)(4) (b)(4) It was agreed that we should asked the sponsor to separate out the recommended treatment procedure based on the indications, specifically in three categories: for minimizing pain and thermal injury during laser and dermatological treatments, for hot/cold therapy, and for massage therapy. Subsequently, the submission was put on hold again on March 28, 2008 for further information on substantial equivalence, directions for use and Zeltiq coupling gel.

This subject supplement (K080118/S2) received on April 28, 2008 is in response to this additional information request. In this supplement, the sponsor has adequately responded to all the deficiencies. An **SE** is recommended.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	x		
Truthful and Accuracy Statement	x		
510(k) Summary or 510(k) Statement	x		
Standards Form			

The sponsor has provided the required certification of compliance for clinical trials (Form 3674). No clinical data has been referenced by this submission.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?	x		
Is the device sterile?		x	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	x		

The Zeltiq CLN1 Dermal Cooling Device consists of the following components:

- Applicators;
- Applicator Sleeves;
- Portable control unit containing the control and power system; and
- User Interface.

This device is a thermoelectric device that applies a user selected treatment profile in a controlled manner to a treatment site. It includes design enhancements to the predicate, Juniper CLN1 Dermal Cooling Device (K072152), as follows:

- An alternate vacuum applicator design. It includes the use of a vacuum to provide the massage feature. The vacuum applicator also draws tissue into the applicator during the cooling treatment.
- Inclusion of a (b)(4) (b)(4) for use with the coupling gel.
- Hardware modification to include a transmitter system for support of an accessory pager.
- Software upgrades to include the enhancements to the user interface.

The Zeltiq CLN1 Cooling Device, including the applicators and disposable sleeves, are sold non-sterile. Cleaning instruction is included in the Direction for Use: Zeltiq CLN1 Dermal Cooling Device.

III. Indications for Use

The Zeltiq CLN1 Cooling Device is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that include minor local discomfort. The Zeltiq CLN1 Cooling Device can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.
The Zeltiq Coupling Gels facilitate thermal contact of the Zeltiq CLN1 Dermal Cooling Device with a patient's skin by mitigating minor variances in device-to-skin contact.

This indication statement is the same as that of the predicate, Juniper CLN1 Dermal Cooling Device (K072152). No change in the intended use also.

IV. Predicate Device Comparison

The sponsor has proposed the following predicates: Juniper CLN1 Dermal Cooling Device (K072152), MediSeb ElfCare thermal therapy device (K023231) for the intended use and mechanism of action; Cynosure Triactive Therapeutic massager (K030876) for the massager; Cynosure Triactive Therapeutic Massage System (K030876) and LPG USA (K990445) for the vacuum applicator and Spacelabs Ultraview Waveform Pager System (K992749) for the pager.

The sponsor has updated the substantial equivalence comparison table to include the comparison of the indications for use, principle of operation, function and features with additional predicates, LPG USA, K990445, and Syneron Vesasmooth, K070092 (Attachment 1, K080118/S2). This revised comparison table has the predicate, Juniper CLN1 Dermal Cooling Device (K072152) with the same indication for the temporary reduction of cellulite appearance It is noted that the Syneron predicate (K070092), and LPG predicate (K990445), although, have the temporary reduction of cellulite appearance indication, they do not have the heating and cooling functions together with the massager. The Cynosure predicate (K030876) includes (b)(4) (b)(4) sources for heating.

The sponsor also updated the substantial equivalence comparison table (Table 2, K080118/S1) to include the comparison specific to the pager system (Spacelabs Ultraview Waveform Pager System, K992749). It compares the indications, principle of operation, and design features.

The proposed device is SE in indications, design configuration, method of operation, and functions to its predicates. The subject device does not change the fundamental scientific technology and do not raise new questions of safety or efficacy.

V. Labeling

The sponsor has provided the package labels and revised Directions for Use for the following:

- Zeltiq CLN1 Dermal Cooling Device
- Zeltiq Aesthetics Vacuum Applicator Single Patient Use Sleeve

The sponsor has revised the directions for use (Attachment 2, K080118/S2) to include the general treatment procedure for different indications, in the following three categories: (b)(4), (b)(5) (b)(4), (b)(5)
(b)(4), (b)(5)

(b)(4), (b)(5)

The labeling are found to be adequate.

VI. Sterilization/Shelf Life/Reuse

The Zeltiq CLN1 Cooling Device, including the applicators and disposable sleeves, are sold non-sterile. The sleeves and (b)(4), (b)(5) are intended for single use and are disposable after each procedure.

VII. Biocompatibility

According to the sponsor, the only new patient contacting materials introduced in this design upgrade are (b)(4) (b)(4) and the (b)(4) (b)(4) used with the coupling gel at the interface between the applicator and the skin.

(b)(4)

(b)(4)

VIII. Software

Version: Rev. 08, Jan 11, 2008

Level of Concern: Moderate

	Yes	No
Software description: (Attachment 18-1)	x	
Device Hazard Analysis: (Attachments 18-2 and 18-3)	x	
Software Requirements Specifications: (Attachment 18-4)	x	
Architecture Design Chart: (Attachment 18-1)	x	
Design Specifications: (Attachment 18-1)	x	
Traceability Analysis/Matrix: (Attachment 18-5)	x	
Development: (Attachment 18-7)	x	
Verification & Validation Testing: (Attachments 18-5 and 18-6)	x	
Revision level history: (page 103)	x	
Unresolved anomalies: (Section 8, Attachment 18-5)	x	

The changes in the software from that of the predicate, Juniper CLN1 Dermal Cooling Device (K072152) include the following:

- (b)(4)
- (b)(4)
- Use of an optional pager that notifies the user of device status during treatment such as when the treatment is complete or if a system error occurs.

VIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The sponsor stated that the following electromagnetic and electrical safety testing is being conducted:

(b)(4), (b)(5)

(b)(4), (b)(5)

IX. Performance Testing – Bench

The sponsor has conducted the verification tests for the vacuum applicator and the disposable sleeves. Test results are provided (Attachments 20-1 and 20-2, K080118).

X. Performance Testing – Animal

XI. Performance Testing – Clinical

XII. Substantial Equivalence Discussion

	Yes	No	
1. Is Product A Device	x		If **NO** = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	x		If **NO** = Stop, see 510(k) staff
3. Same Indication Statement?	x		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
5. Same Technological Characteristics?	x		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?	x		If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification 510kProgram/0_4147/FLOWCHART 510K DECISION.PDF for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. Explain how the new indication differs from the predicate device's indication:
   Please see section III and IV

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XIII. Deficiencies

The sponsor has adequately responded to all the deficiencies in the AI letter dated March 28, 2008 as follows:

1) Substantial Equivalence
In your response to deficiency #1 in FDA's letter dated February 27, 2008, you have provided a substantial equivalence matrix for the vacuum applicator (Table 1, K080118/S1) with additional substantial equivalence matrix for the Zeltiq CLN1 Dermal Cooling Device (Table 1, K080118) to include these two predicates. Please provide a revised substantial equivalence matrix for the Zeltiq CLN1 Dermal Cooling Device to include these two new predicates, if they are applicable.

Response:
The sponsor has updated the substantial equivalence comparison table to include the comparison of the indications for use, principle of operation, function and features with additional predicates, LPG USA, K990445, and Syneron Vesasmooth, K070092 (Attachment 1, K080118/S2). This revised comparison table is adequate.

2) Directions for Use
In your revised directions for use for the PL10691-D Zeltiq CLN1 Dermal Cooling Device (Attachment 2, K080118/S1), you did not include any treatment procedure recommended for different indications, specifically in three categories: for minimizing pain and thermal injury during laser and dermatological treatments, for hot/cold therapy, and for massage therapy. Please revise your directions for use to include the general treatment procedure recommended for minimizing pain and thermal injury during laser and dermatological treatments, for hot/cold therapy, and for massage therapy.

Response:
The sponsor has revised the directions for use (Attachment 2, K080118/S2) to include the general treatment procedure for different indications, in the following three categories: for minimizing pain and thermal injury during laser and dermatological treatments, for hot/cold therapy, and for massage therapy. For example, (b)(4), (b)(5) (b)(4), (b)(5) (b)(4), (b)(5) (b)(4), (b)(5) profiles are found to be acceptable (Table 1, Attachment 2, K080118/S2).

3) Zeltiq Coupling Gel
In your response to deficiency #7, you indicate that the Zeltiq Coupling Gel is the same gel that was previously named the Juniper Coupling Gel. However, you did not clarify whether the Zeltiq Coupling Gel is the gel 400 or gel 600 in the predicate, Juniper CLN1 Dermal Cooling Device (K072152). Please clarify.

Response:
The sponsor clarified that the Zeltiq Coupling Gel is the same gel that was previously named the Juniper Coupling Gel (K063715). This gel is different from the Zeltiq Coupling Gel 400 or gel 600 in the predicate K072152.

XIV. Contact History

A telephone conversation with the sponsor (Donald V Johnson) followed up by an e-mail on 2/27/2008 asking for additional information.
A telephone message left with the sponsor (Donald V Johnson) followed up by an e-mail on 3/28/2008 asking for additional information.

Further clarification with the sponsor (Bryan Olin) on 4/16, 4/17 and 4/23/2008.

XV. Recommendation

Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Instrument, Surgical, Powered
Regulatory Class: Class II
Product Code: GEX
Additional Product Code: ILO, ISA

Long Chen
Lead Reviewer, GSDB/DGRND

4/30/08
Date

~~Neil Ogden~~ TINA KIANG
Branch Chief, GSDB/DGRND
(ACTING)

5/1/08
Date

Chen, Long H

From: Bryan Olin [bolin@zeltiq.com]
Sent: Wednesday, April 23, 2008 3:57 PM
To: Chen, Long H
Cc: Donald Johnson
Subject: RE: Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118): Supplemental information request (4/16/08)

Dr. Chen-

Thank you for the message. We will prepare and send a hard copy response to the document mail center.

We understand your comment that accepting the rationale for safety does not imply support for any other indication.

Regarding the 5 vs. 6 patients, there are actually 6 patients listed in the report who were treated with (b)(4) (b)(4) (b)(4) (b)(4) These six patients are (b)(4) (b)(4) I had a typo in the email below.

Bryan Olin, Ph.D.
Senior Director, Quality Assurance
Zeltiq Aesthetics
4698 Willow Road
Pleasanton, CA 94588
(b)(4)
(b)(4)

From: Chen, Long H [mailto:long.chen@fda.hhs.gov]
Sent: Wednesday, April 23, 2008 9:48 AM
To: Bryan Olin
Subject: RE: Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118): Supplemental information request (4/16/08)

Bryan,

Your response is acceptable. Please send in your hard copy response to our document mail center.
However, I want to point out that your Prospective Clinical Study of (b)(4) (b)(4)
(b)(4)
(b)(4)
(b)(4) (b)(4)
Also, the data contains only 5 (five) patients, not 6 patients as stated, that were treated with a (b)(4) (b)(4)
(b)(4) (b)(4)

Long
Long Chen, Ph.D.
(240)276-3628
G[illegible]B/DGRND/ODE
l[illegible]chen@fda.hhs.gov

From: Bryan Olin [mailto:bolin@zeltiq.com]

Sent: Tuesday, April 22, 2008 2:06 PM
To: Chen, Long H
Cc: Donald Johnson
Subject: RE: Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118): Supplemental information request (4/16/08)

Dr. Chen-

To facilitate your review, I have replied to each of your requests in turn below.

1. (b)(4) (b)(4)
and provide justifications why it is safe to use under the proposed (b)(4) (b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

2. **Please make it clear in your** (b)(4) **that there will be a** (b)(4) (b)(4) (b)(4) (b)(4)

Please see the revised description of (b)(4) (b)(4) of the attached directions for use which includes this information.

3. **Please clarify in your** (b)(4) **to include** (b)(4) (b)(4)

Please see the revised description of (b)(4) (b)(4) of the attached directions for use which includes this information.

Regards,

Bryan

Bryan Olin, Ph.D.
Senior Director, Quality Assurance

16

Zeltiq Aesthetics
4698 Willow Road
Pleasanton, CA 94588
(b)(3)
(b)(3)

From: Chen, Long H [mailto:long.chen@fda.hhs.gov]
Sent: Thursday, April 17, 2008 7:11 AM
To: Bryan Olin
Subject: RE: Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118): Supplemental information request (4/16/08)

Bryan,

Thank you for the information. However, I want to bring it up to your attention that (b)(4) (b)(4) (b)(4) (b)(4) It does not apply to your massage indication.
Also, (b)(4) (b)(4)
(b)(4) (b)(4)
Therefore,

(b)(4)
(b)(4)

Long
Long Chen, Ph.D.
(240)276-3628
GSDB/DGRND/ODE/FDA
long.chen@fda.hhs.gov

From: Bryan Olin [mailto:bolin@zeltiq.com]
Sent: Wednesday, April 16, 2008 6:51 PM
To: Chen, Long H
Cc: Donald Johnson
Subject: Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118): Supplemental information request (4/16/08)

Dr. Chen-

Per our phone discussion today, I understood that we have two final issues to work through which I will address in this note.

1. **Zeltiq still needs to be more specific in** (b)(4) (b)(4) **For example, you indicated that you were under the impression that** (b)(4) (b)(4)

   We revised the (b)(4) (b)(4) the (b)(4) (b)(4) in our directions for use, PL10691-E CLN1 DFU, as follows:

   (b)(4) (b)(4) may be available for selection by the user (Figure 7) in the Settings mode. (b)(4) (b)(4)
   (b)(4)
   (b)(4)

The underlined text above represents the revised section that provides additional detail of what happens during (b)(4) (b)(4)

2. **Concerns regarding the (b)(4) (b)(4) For example, you indicated that we should provide predicates or data to support this.**

As indicated in our discussion, I reviewed our previous submissions. In each of the past two cleared submissions, K072152 and K063715, and in our current submission, K080118, we have included the MediSeb ElfCare thermal therapy device for both hot and cold applications (K023231) as a predicate device. I believe that our substantial equivalence to this device supports (b)(4) (b)(4)

Note that as described by the Elf Care labeling included in the submission (attached as ElfCare brochure.pdf), the Elf Care device allows (b)(4) (b)(4) (b)(4) (b)(4)

- (b)(4)
- (b)(4)

In addition, ElfCare labeling on the MediSeb website, www.mediseb.com (attached as ElfCare Website.pdf with quotes highlighted in yellow) indicates that: (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4)

Hence, we believe that the ElfCare predicate we provided in this and previous submissions supports the (b)(4) (b)(4) (b)(4) (b)(4) than those previously cleared for the ElfCare device under K023231.

I believe that these comments should address the concerns of which we spoke this morning. As always, please do not hesitate to contact me should you have additional questions.

Bryan Olin, Ph.D.
Senior Director, Quality Assurance
Zeltiq Aesthetics
4698 Willow Road
Pleasanton, CA 94588
(b)(4) (b)(4)

From: Bryan Olin
Sent: Wednesday, April 16, 2008 9:35 AM
To: 'Chen, Long H'
Cc: Donald Johnson
Subject: RE: Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118): Supplemental information request (4/11/08)

Dr. Chen-

As I mentioned in my voice mail, the (b)(4) (b)(4)

Regards,

Bryan

Bryan Olin, Ph.D.
Senior Director, Quality Assurance
Zeltiq Aesthetics
4698 Willow Road
Pleasanton, CA 94588
(b)(4)
(b)(4)

From: Chen, Long H [mailto:long.chen@fda.hhs.gov]
Sent: Wednesday, April 16, 2008 6:16 AM
To: Bryan Olin
Subject: RE: Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118): Supplemental information request (4/11/08)

Bryan,

(b)(4)
(b)(4)

Long
Long Chen, Ph.D.
(240)276-3628
GSDB/DGRND/ODE/FDA
long.chen@fda.hhs.gov

From: Bryan Olin [mailto:bolin@zeltiq.com]
Sent: Tuesday, April 15, 2008 2:18 PM
To: Chen, Long H
Cc: Donald Johnson
Subject: Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118): Supplemental information request (4/11/08)

Dr. Chen-

As discussed via telephone on 4/11/08, you indicated that you needed an appropriate predicate device in order to clear our device's usage (b)(4) (b)(4)
(b)(4) (b)(4)

To answer this question, we have reproduced Table 3 (page 30) from our submission K063715 (Juniper XTRA with massage function), which lists a number of predicate devices.

We note that this table lists (b)(4) predicate devices (b)(4) (b)(4)
(b)(4) (b)(4)
(b)(4) (b)(4)

Table 3. Cleared devices with the indication "temporarily reduces the appearance of cellulite."

	510(k)	Product		

Device	Number	Code	Classification	Technological
Thermassage	K061001	ISA	§890.5660	Massage – suction
TriActive Therapeutic Massage System	K030876	ISA	§890.5660	Heating – laser (808nm) Massage – suction
Dermosonic Non-invasive Subdermal Therapy System	K052934	ISA	§890.5660	Heating – ultrasound Massage – suction
Biocellulase Smoothshapes	K061603	NUV	§878.4810	Heating – laser Massage – rollers & suction
Velasmooth Shaper	K050397	NUV	§878.4810	Heating – infrared light & RF energy Massage – rollers & suction

ISA - massager, therapeutic, electric
NUV - massager, vacuum, light induced heating

The summaries of safety and effectiveness for these two devices reinforce that (b)(4) (b)(4) (b)(4) (b)(4) as follows (we added the bold/underline):

- (b)(4) (b)(4)
- (b)(4) (b)(4)

For your convenience, we have also attached the summaries of safety and effectiveness for both devices.

We believe that this provides the appropriate predicate information to allow clearance (b)(4) (b)(4) (b)(4) (b)(4)

Please do not hesitate to contact me should you have any additional questions.

Regards,

Bryan

Bryan Olin, Ph.D.
Senior Director, Quality Assurance
Zeltiq Aesthetics
4698 Willow Road
Pleasanton, CA 94588
(b)(4) (b)(4)

Chen, Long H

From: Chen, Long H
Sent: Thursday, April 17, 2008 10:11 AM
To: 'Bryan Olin'
Subject: RE: Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118): Supplemental information request (4/16/08)

Bryan,

Thank you for the information. However, I want to bring it up to your attention that the (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4)
Therefore,

(b)(4) (b)(4)

Long
Long Chen, Ph.D.
(240)276-3628
GSDB/DGRND/ODE/FDA
lo chen@fda.hhs.gov

From: Bryan Olin [mailto:bolin@zeltiq.com]
Sent: Wednesday, April 16, 2008 6:51 PM
To: Chen, Long H
Cc: Donald Johnson
Subject: Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118): Supplemental information request (4/16/08)

Dr. Chen-

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1. **Zeltiq still needs to be more specific** (b)(4) (b)(4) **For example, you indicated that you were under the impression that** (b)(4) (b)(4)

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   (b)(4) (b)(4)

   The underlined text above represents the revised section that provides additional detail of what happens (b)(4) (b)(4) (b)(4) (b)(4)

2. **Concerns regarding the** (b)(4) (b)(4) **For example, you indicated that we should provide predicates or data to support this.**

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Note that as described by the Elf Care labeling included in the submission (attached as ElfCare brochure.pdf), the Elf Care device allows (b)(4) (b)(4) (b)(4) (b)(4) highlighted in yellow in the attachment:

- (b)(4)
- (b)(4)

In addition, ElfCare labeling on the MediSeb website, www.mediseb.com with (b)(4) (b)(4) (b)(4) (b)(4)

Hence, we believe that the ElfCare predicate we provided in this and previous submissions supports the safety of (b)(4) (b)(4) (b)(4) (b)(4) than those previously cleared for the ElfCare device under K023231.

I believe that these comments should address the concerns of which we spoke this morning. As always, please do not hesitate to contact me should you have additional questions.

Bryan Olin, Ph.D.
Senior Director, Quality Assurance
Zeltiq Aesthetics
4698 Willow Road
Pleasanton, CA 94588
(b)(4) (b)(4)

From: Bryan Olin
Sent: Wednesday, April 16, 2008 9:35 AM
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Subject: RE: Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118): Supplemental information request (4/11/08)

Dr. Chen-

As I mentioned in my voice mail, (b)(4) (b)(4)

Regards,

Bryan

Bryan Olin, Ph.D.
Senior Director, Quality Assurance
Zeltiq Aesthetics

4698 Willow Road
Pleasanton, CA 94588
(b)(4)
(b)(4)

From: Chen, Long H [mailto:long.chen@fda.hhs.gov]
Sent: Wednesday, April 16, 2008 6:16 AM
To: Bryan Olin
Subject: RE: Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118): Supplemental information request (4/11/08)

Bryan,

Regarding to your proposed (b)(4) (b)(4) please clarify (b)(4) (b)(4) If this is the case, you need to provide (b)(4) (b)(4). Thanks.

Long
Long Chen, Ph.D.
(240)276-3628
GSDB/DGRND/ODE/FDA
long.chen@fda.hhs.gov

From: Bryan Olin [mailto:bolin@zeltiq.com]
Sent: Tuesday, April 15, 2008 2:18 PM
To: Chen, Long H
Cc: Donald Johnson
Subject: Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118): Supplemental information request (4/11/08)

Dr. Chen-

As discussed via telephone on 4/11/08, you indicated that you needed an appropriate predicate device in order to clear our device's (b)(4) (b)(4) (b)(4) (b)(4).

To answer this question, we have reproduced Table 3 (page 30) from our submission K063715 (Juniper XTRA with massage function), which lists a number of predicate devices.

We note that this table lists two predicate devices that (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) K080118.

Table 3. Cleared devices with the indication "temporarily reduces the appearance of cellulite."

Device	510(k) Number	Product Code	Classification	Technological
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Dermosonic Non-invasive Subdermal Therapy System	K052934	ISA	§890.5660	Heating – ultrasound

				Massage – suction
Biocellulase Smoothshapes	K061603	NUV	§878.4810	Heating – laser Massage – rollers & suction
Velasmooth Shaper	K050397	NUV	§878.4810	Heating – infrared light & RF energy Massage – rollers & suction

ISA - massager, therapeutic, electric
NUV - massager, vacuum, light induced heating

The summaries of safety and effectiveness for these two devices reinforce that they (b)(4) (b)(4) (b)(4) (b)(4) as follows (we added the bold/underline):

- (b)(4) (b)(4)
- (b)(4) (b)(4)

For your convenience, we have also attached the summaries of safety and effectiveness for both devices.

We believe that this provides the appropriate predicate information to (b)(4) (b)(4) (b)(4) (b)(4)

Please do not hesitate to contact me should you have any additional questions.

Regards,

Bryan

Bryan Olin, Ph.D.
Senior Director, Quality Assurance
Zeltiq Aesthetics
4698 Willow Road
Pleasanton, CA 94588
(b)(4) (b)(4)

Chen, Long H

From: Chen, Long H
Sent: Wednesday, April 16, 2008 9:16 AM
To: 'Bryan Olin'
Subject: RE: Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118): Supplemental information request (4/11/08)

Bryan,

Regarding to your proposed (b)(4) (b)(4) please clarify whether (b)(4) (b)(4) If this is the case, you need to provide (b)(4) (b)(4) Thanks.

Long
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long.chen@fda.hhs.gov

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Sent: Tuesday, April 15, 2008 2:18 PM
To: Chen, Long H
Cc: Donald Johnson
Subject: Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118): Supplemental information request (4/11/08)

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We note that this table lists two predicate devices that (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) K080118.

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Dermosonic Non-invasive Subdermal Therapy System	K052934	ISA	§890.5660	Heating – ultrasound Massage – suction
Biocellulase Smoothshapes	K061603	NUV	§878.4810	Heating – laser Massage – rollers & suction
				Heating – infrared light & RF

Velasmooth Shaper	K050397	NUV	§878.4810	energy Massage – rollers & suction

ISA - massager, therapeutic, electric
NUV - massager, vacuum, light induced heating

The summaries of safety and effectiveness for these two devices reinforce that (b)(4) (b)(4) (b)(4) as follows (we added the bold/underline):

- (b)(4) (b)(4)
- (b)(4) (b)(4)

For your convenience, we have also attached the summaries of safety and effectiveness for both devices.

We believe that this provides the appropriate predicate information to (b)(4) (b)(4) (b)(4)

Please do not hesitate to contact me should you have any additional questions.

Regards,

Bryan

Bryan Olin, Ph.D.
Senior Director, Quality Assurance
Zeltiq Aesthetics
4698 Willow Road
Pleasanton, CA 94588
(b)(4) (b)(4)

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Long Chen

Subject: 510(k) Number K080185

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☒ Hold (Additional Information or Telephone Hold)

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)?			X
Does this device include an Animal Tissue Source?			X
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number	Class*	Product Code
21 CFR 878.4810	II	GEX

(*If unclassified, see 510(k) Staff)

Additional Product Codes: ILO, ISA

Review: [signature] (Branch Chief) GSDB (Branch Code) 3/28/08 (Date)

Final Review: _____ (Division Director) (Date)

Rev. 5/30/07

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K080118/S1

Date: March 28, 2008
To: The Record
From: Long Chen, Ph.D. Chemical Engineer

Office: ODE
Division: DGRND/GSDB

510(k) Holder: Zeltiq Aesthetics, Pleasanton, CA
Device Name: **Zeltiq Aesthetics CLN1 Dermal Cooling Device**
Contact: Donald V Johnson, VP Operations, Regulatory, & Quality Affairs
Phone: 925-474-2509
Fax: 925-474-2599
Email: djohnson@zeltiq.com

I. Purpose

The 510(k) holder would like to introduce the subject modified Zeltiq Aesthetics CLN1 Dermal Cooling Device into interstate commerce.

This device has been previously cleared as Juniper CLN1 Dermal Cooling Device (K072152). In this submission, the sponsor has made an upgrade to the accessories and software. In addition, the sponsor noted that Juniper Medical, Inc. has changed the company name to Zeltiq Aesthetics, Inc. as of July 31, 2007.

This device is for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. It can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. In addition, the massage function can be used for the relief of minor muscle aches, pain and spasm and for the improvement in local circulation and temporary reduction in the appearance of cellulite. According to the sponsor, the upgrade was implemented

- to include a vacuum applicator that provides pulsatile message;
- to use a (b)(4), (b)(5) with the Zeltiq gel as the interface between the applicator sleeve and the skin;
- to modify the hardware and software to include a transmitter system that supports a pager.

Furthermore, the sponsor indicated that the treatment parameters will be the same as the predicate, Juniper CLN1 Dermal Cooling Device (K072152). This includes the treatment temperature from (b)(4), (b)(5) (b)(4), (b)(5) the maximum application time from (b)(4), (b)(5) and the maximum applicator interface surface area of (b)(4), (b)(5) The range of the vacuum pressure will be from (b)(4), (b)(5) The verification test for the vacuum applicator was conducted and the results are also provided.

In this supplement, the sponsor has addressed some of the deficiencies identified in the telephone hold letter dated February 27, 2008, in the following areas: substantial equivalence, vacuum applicator, paging system, wireless technology, electrical safety test, and cleaning instruction. However, the sponsor has not included any general treatment procedure for different indications in

the directions for use.

I had a discussion with Neil Ogden, Branch Chief, GSDB/DGRND, and Richard Felten, GSDB/DGRND, on 3/28/2008. It was agreed that we should asked the sponsor to separate out the recommended treatment procedure based on the indications, specifically in three categories: for minimizing pain and thermal injury during laser and dermatological treatments, for hot/cold therapy, and for massage therapy. As a result, the deficiencies are identified in section XIII and need to be clarified.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	x		
Truthful and Accuracy Statement	x		
510(k) Summary or 510(k) Statement	x		
Standards Form			

The sponsor has provided the required certification of compliance for clinical trials (Form 3674). No clinical data has been referenced by this submission.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?	x		
Is the device sterile?		x	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	x		

The Zeltiq CLN1 Dermal Cooling Device consists of the following components:

- Applicators;
- Applicator Sleeves;
- Portable control unit containing the control and power system; and
- User Interface.

This device is a thermoelectric device that applies a user selected treatment profile in a controlled manner to a treatment site. It includes design enhancements to the predicate, Juniper CLN1 Dermal Cooling Device (K072152), as follows:

- An alternate vacuum applicator design. It includes the use of a vacuum to provide the massage feature. The vacuum applicator also draws tissue into the applicator during the cooling treatment.
- Inclusion of a (b)(4), (b)(5) for use with the coupling gel.
- Hardware modification to include a transmitter system for support of an accessory pager.
- Software upgrades to include the enhancements to the user interface.

The Zeltiq CLN1 Cooling Device, including the applicators and disposable sleeves, are sold non-sterile. Cleaning instruction is included in the Direction for Use: Zeltiq CLN1 Dermal Cooling Device.

III. Indications for Use

The Zeltiq CLN1 Cooling Device is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that include minor local discomfort. The Zeltiq CLN1 Cooling Device can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the relief of minor muscle aches, pain, and spasm and for the improvement in local circulation and in the temporary reduction in the appearance of cellulite.
The Zeltiq Coupling Gels facilitate thermal contact of the Zeltiq CLN1 Dermal Cooling Device with a patient's skin by mitigating minor variances in device-to-skin contact.

This indication statement is the same as that of the predicate, Juniper CLN1 Dermal Cooling Device (K072152). No change in the intended use also.

IV. Predicate Device Comparison

(b)(4), (b)(5)

(b)(4), (b)(5)

V. Labeling

The sponsor has provided the package labels and revised Directions for Use for the following:

- Zeltiq CLN1 Dermal Cooling Device
- Zeltiq Aesthetics Vacuum Applicator Single Patient Use Sleeve

However, the sponsor has not included any general treatment procedure for different indications in the directions for use, specifically in three categories: for minimizing pain and thermal injury during laser and dermatological treatments, for hot/cold therapy, and for massage therapy. See new deficiency #2.

VI. Sterilization/Shelf Life/Reuse

The Zeltiq CLN1 Cooling Device, including the applicators and disposable sleeves, are sold non-sterile. The sleeves and (b)(4), (b)(5) are intended for single use and are disposable after each procedure.

VII. Biocompatibility

According to the sponsor, the only new patient contacting materials introduced in this design upgrade are the (b)(4), (b)(5) on the applicator sleeve and the (b)(4), (b)(5) pad used with the coupling gel at the interface between the applicator and the skin.
Since (b)(4), (b)(5) has a long history of similar use in the medical device, the sponsor performed a cytotoxicity test on a sample of (b)(4), (b)(5) film used for the applicator sleeve. No evidence of any cell lysis or toxicity,

using the ISO elution method, was reported.
The sponsor also stated that the (b)(4), (b)(5) is currently marketed as a Class I medical device as an orthopedic accessory for casting (b)(4), (b)(5) (b)(4), (b)(5)

VIII. Software

Version: Rev. 08, Jan 11, 2008		
Level of Concern: Moderate		
	Yes	**No**
Software description: (Attachment 18-1)	x	
Device Hazard Analysis: (Attachments 18-2 and 18-3)	x	
Software Requirements Specifications: (Attachment 18-4)	x	
Architecture Design Chart: (Attachment 18-1)	x	
Design Specifications: (Attachment 18-1)	x	
Traceability Analysis/Matrix: (Attachment 18-5)	x	
Development: (Attachment 18-7)	x	
Verification & Validation Testing: (Attachments 18-5 and 18-6)	x	
Revision level history: (page 103)	x	
Unresolved anomalies: (Section 8, Attachment 18-5)	x	

The changes in the software from that of the predicate, Juniper CLN1 Dermal Cooling Device (K072152) include the following:

- Monitoring and feedback on the quality of the contact between the applicator and the skin prior to and during treatment;
- Monitoring and feedback on the detection of a freeze event during treatment including automatic shut off the device if a freeze event is detected; and
- Use of an optional pager that notifies the user of device status during treatment such as when the treatment is complete or if a system error occurs.

VIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The sponsor stated that the following electromagnetic and electrical safety testing is being conducted:
(b)(4), (b)(5)
(b)(4), (b)(5)
(b)(4), (b)(5)
(b)(4), (b)(5)

IX. Performance Testing – Bench

The sponsor has conducted the verification tests for the vacuum applicator and the disposable sleeves. Test results are provided (Attachments 20-1 and 20-2, K080118).

X. Performance Testing – Animal

XI. Performance Testing – Clinical

XII. Substantial Equivalence Discussion

	Yes	No	
1. Is Product A Device	x		If **NO** = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	x		If **NO** = Stop, see 510(k) staff
3. Same Indication Statement?	x		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
5. Same Technological Characteristics?			If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?			If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification 510kProgram/0_4147/FLOWCHART 510K DECISION.PDF for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. Explain how the new indication differs from the predicate device's indication:
   Please see section III and IV

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XIII. Deficiencies

1) Substantial Equivalence

(b)(4), (b)(5)

(b)(4), (b)(5)

b. Please revise the Substantial Equivalence tables to include detailed information of each category and identify relevant similarities and differences.
c. Please provide additional predicate(s) for some of the different features, or
d. Please provide data and/or rationale to justify that the differences do not adversely affect the safety and effectiveness of your device.

Response:
The sponsor has updated the substantial equivalence comparison table (Table 1, K080118/S1) to include the comparison specific to the vacuum applicator (Cynosure Triactive Therapeutic Massage System, K030876; LPG USA, K990445; and Syneron Velasmooth, K070092). It compares the vacuum functions, massage, message with simultaneous heating, massage/cooling, console, pulsatile vacuum, suction power, frequency, cycle rate, power source, sterility and reusable.

However, the indications for use was not included in the comparison, specifically, the comparison of the indication for the temporary reduction of cellulite appearance. The Syneron predicate (K070092) is not a valid predicate due to the difference in the indication (for temporary reduction of thighs circumferences). LPG predicate (K990445), although has the temporary reduction of cellulite appearance indication, it does not have the heating and cooling functions together with the massager. The Cynosure predicate (K030876) includes six 808nm IR sources for heating. See new deficiency #1.

In addition, the sponsor has not included any general treatment procedure for different indications in the directions for use, specifically in three categories: for minimizing pain and thermal injury during laser and dermatological treatments, for hot/cold therapy, and for massage therapy. See new deficiency #2.

The sponsor also updated the substantial equivalence comparison table (Table 2, K080118/S1) to include the comparison specific to the pager system (Spacelabs Ultraview Waveform Pager System, K992749). It compares the indications, principle of operation, and design features.

2) Vacuum Applicator
You indicate that an alternate vacuum applicator with the massage feature is included in this device. However, the information you provided for the vacuum applicator is not adequate.
a. Please describe in detail the functions and features of the vacuum applicator.
b. (b)(4), (b)(5) (b)(4), (b)(5)
c. Please discuss the safety features incorporated with the vacuum applicator.
d. Please provide a predicate for applying vacuum together with warm or cold massage; or
e. Please provide data and/or justification to demonstrate the safe use of vacuum applicator during warm or cold massage.

Response:
(b)(4), (b)(5)

(b)(4), (b)(5)

3) Paging System

You indicate that an optional paging system has been added to provide a secondary system to notify staff of system status. However, the information you provided for this paging system is not adequate.

a. Please describe in detail the components, functions and features of the paging system.
b. Please provide an overall hardware configuration diagram that includes this optional paging system.
c. Please include in your Software Architecture Design Chart (page 110) how the paging system will interface with the rest of the software system.
d. Please indicate whether the wireless communication is used between the transmitter and the pager.
e. Please include in your Direction for Use a section related to the paging system.

Response:
The paging system is to provide a secondary system to notify staff of system status: when a treatment session is cancelled, procedure completion or system error. The sponsor has updated the software architecture design chart (Attachment 3, K080118/S1) and the directions for use (Attachment 2, K080118/S1) to include the paging system.

4) Wireless Technology
If wireless technology is used in your paging system, please address the following issues:

a. How users will interact with the system.
b. For wireless devices that use computer programs ("software"), the program's ability to handle the device responses and/or failures under EMI conditions
c. All functions that the wireless device will perform, and all safety-related requirements, specifications, features, and functions that will be implemented wirelessly
d. Wireless protocol specification name or designation (e.g., WMTS, IEEE 802.11b) for all wireless technologies incorporated into the device.
e. Wireless transmitter/receiver parameters such as operating frequency, output power, etc.
f. All coexistence, data integrity (e.g., data throughput, latency) and security features and performance requirements that the wireless system will meet.
g. Data security features to prevent unauthorized access to data or networks

Response:
(b)(4), (b)(5)

(b)(4), (b)(5)

5) Electrical Safety Test
In Section 19, Electromagnetic Compatibility and Electrical Safety, you indicate that the following electromagnetic and electrical safety testing is being conducted: (b)(4), (b)(5) (b)(4), (b)(5)
(b)(4)

(b)(4)

Response:
The sponsor stated that the paging system will be included in the electrical safety test that complies with (b)(4), (b)(5) (b)(4), (b)(5)

6) Cleaning Instruction
In Section 16, Sterilization & Shelf Life, you indicate that the applicators and disposable sleeves are not sold sterile. However, in your Direction for Use: Zeltiq Aethetics Vacuum Applicator Single Patient Use Sleeve, you did not address and/or provide instructions how to keep the sleeves and (b)(4), (b)(5) clean prior to use. Please clarify and revise your labeling accordingly.

Response:

The sponsor clarified that the sleeves and (b)(4), (b)(5) are intended for single use and are disposable after each procedure.

7) Zeltiq Coupling Gel
You indicate in the labeling that Zeltiq Coupling Gel is applied to the patient prior to use of the system. However, you have not provided any information regarding to the Zeltiq Coupling Gel.

a. Please compare the Zeltiq Coupling Gel with (b)(4), (b)(5) in the predicate, Juniper CLN1 Dermal Cooling Device (K072152). If they are different,
b. Please provide detailed information of the Zeltiq Coupling Gel, including the manufacturing process, common and/or trade names of each chemical, etc..
c. Please provide predicate(s) for this Zeltiq Coupling Gel, or
d. Please provide data to demonstrate the safety and efficacy of the Zeltiq Coupling Gel.

Response:
The sponsor clarified that the Zeltiq Coupling Gel is the same gel that was previously named the Juniper Coupling Gel. However, the sponsor did not indicate whether the Zeltiq Coupling Gel is the gel 400 or gel 600 in the predicate, Juniper CLN1 Dermal Cooling Device (K072152). See new deficiency #3.

New Deficiencies
Consequently, new deficiencies will need to be clarified by the sponsor. They are summarized as follows:

1) Substantial Equivalence
(b)(4), (b)(5)

(b)(4), (b)(5)

2) Directions for Use
In your revised directions for use for the PL10691-D Zeltiq CLN1 Dermal Cooling Device (Attachment 2, K080118/S1), you did not include any treatment procedure recommended for different indications, specifically in three categories: for minimizing pain and thermal injury during laser and dermatological treatments, for hot/cold therapy, and for massage therapy. Please revise your directions for use to include the general treatment procedure recommended for minimizing pain and thermal injury during laser and dermatological treatments, for hot/cold therapy, and for massage therapy.

3) Zeltiq Coupling Gel
In your response to deficiency #7, you indicate that the Zeltiq Coupling Gel is the same gel that was previously named the Juniper Coupling Gel. However, you did not clarify whether the Zeltiq Coupling Gel (b)(4), (b)(5) Juniper CLN1 Dermal Cooling Device (b)(4), (b)(5). Please clarify.

XIV. Contact History

A telephone conversation with the sponsor (Donald V Johnson) followed up by an e-mail on 2/27/2008 asking for additional information.
A telephone message left with the sponsor (Donald V Johnson) followed up by an e-mail on 3/28/2008 asking for additional information.

XV. Recommendation

I recommend that this submission be placed on hold pending receipt of the response to the above questions.

Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Instrument, Surgical, Powered
Regulatory Class: Class II
Product Code: GEX
Additional Product Code: ILO, ISA

Long Chen
Lead Reviewer, GSDB/DGRND

3/28/08
Date

Neil Ogden
Branch Chief, GSDB/DGRND

Concur with AT.

3/28/08
Date

Chen, Long H

From: Chen, Long H
ent: Friday, March 28, 2008 10:39 AM
ro: 'djohnson@zeltiq.com'
Subject: 510(k) submission - Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118/S1)

Attachments: k080118.s1_email.1.doc

Don,

I have enclosed a copy of the additional information request for the subject 510 (k) supplement. Feel free to contact me for any further clarification.

k080118.s1_
il.1.doc (69 K

Long
Long Chen, Ph.D.
(240)276-3628
GSDB/DGRND/ODE/FDA
long.chen@fda.hhs.gov

March 28, 2008

Mr. Donald V Johnson
VP Operations, Regulatory, & Quality Affairs
Zeltiq Aesthetics, Pleasanton, CA
Ph#: (b)(4) (b)(4)
Fax#
e-mail: (b)(4) (b)(4)

Re: 510(k) submission - Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118/S1)

Dear Mr. Johnson,

In reviewing the subject supplement, we have the following additional questions that need to be clarified to facilitate our review process:

1) Substantial Equivalence
(b)(4), (b)(5)

(b)(4), (b)(5)

2) Directions for Use
In your revised directions for use for the PL10691-D Zeltiq CLN1 Dermal Cooling Device (Attachment 2, K080118/S1), you did not include any treatment procedure recommended for different indications, specifically in the following categories: for minimizing pain and thermal injury during laser and dermatological treatments, for hot/cold therapy, and for massage therapy. Please revise your directions for use to include the general treatment procedure recommended for minimizing pain and thermal injury during laser and dermatological treatments, for hot/cold therapy, and for massage therapy.

3) Zeltiq Coupling Gel
In your response to deficiency #7, you indicate that the Zeltiq Coupling Gel is the same gel that was previously named the Juniper Coupling Gel. However, you did not clarify whether the Zeltiq Coupling Gel is (b)(4), (b)(5) (b)(4), (b)(5) in the predicate, Juniper CLN1 Dermal Cooling Device (K072152). Please clarify.

The subject submission will be placed on hold pending your response with the requested information. If you need more than 30 days to provide a full and complete response, you should submit a request for an extension of time to Document Mail Center (HFZ 401).

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For further information on how to apply for an extension and for general 510(k) information, please visit the FDA Website at:
http://www.fda.gov/cdrh/devadvice/31435.html#link_6

Sincerely,

Long Chen, Ph.D.
Chemical Engineer
Phone#: (240)276-3600, Fax#: (240)276-3733
General and Surgical Devices Branch
Division of General, Restorative and Neurological Devices
FDA/ODE

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Long Chen

Subject: 510(k) Number K050118

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)?			X
Does this device include an Animal Tissue Source?			X
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number	Class*	Product Code
21 CFR 878.4810	II	GEX

(*If unclassified, see 510(k) Staff)

Additional Product Codes: ILO, ISA

Review: [signature] (Branch Chief) GSDB (Branch Code) 2/28/08 (Date)

Final Review: _____ (Division Director) (Date)

Rev. 5/30/07

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PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		**YES**	**NO**
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)			X
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?			X
3. Does this device type require a PMA by regulation? (Please see management.)			X
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)			X
5. a. Did the firm request expedited review? (See management,)			X
b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html)			
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:		X
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:		X
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			X

Rev. 5/30/07

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K080118

Date: February 27, 2008
To: The Record
From: Long Chen, Ph.D. Chemical Engineer

Office: ODE
Division: DGRND/GSDB

510(k) Holder: Zeltiq Aesthetics, Pleasanton, CA
Device Name: **Zeltiq Aesthetics CLN1 Dermal Cooling Device**
Contact: Donald V Johnson, VP Operations, Regulatory, & Quality Affairs
Phone: 925-474-2509
Fax: 925-474-2599
Email: djohnson@zeltiq.com

I. Purpose

The 510(k) holder would like to introduce the subject modified Zeltiq Aesthetics CLN1 Dermal Cooling Device into interstate commerce.

This device has been previously cleared as Juniper CLN1 Dermal Cooling Device (K072152). In this submission, the sponsor has made an upgrade to the accessories and software. In addition, the sponsor noted that Juniper Medical, Inc. has changed the company name to Zeltiq Aesthetics, Inc. as of July 31, 2007.

This device is for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. It can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. According to the sponsor, the upgrade was implemented

- to include a vacuum applicator that provides pulsatile message;
- to use a (b)(4), (b)(5) with the Zeltiq gel as the interface between the applicator sleeve and the skin;
- to modify the hardware and software to include a transmitter system that supports a pager.

Furthermore, the sponsor indicated that the treatment parameters will be the same as the predicate, Juniper CLN1 Dermal Cooling Device (K072152). This includes the treatment temperature from (b)(4), (b)(5) (b)(4), (b)(5) the maximum application time from (b)(4), (b)(5) and the maximum applicator interface surface area of (b)(4), (b)(5) However, the range of the vacuum pressure has not been addressed.

Although the sponsor has conducted the verification test for the vacuum applicator, the information provided for the vacuum applicator and the paging system are not adequate. As a result, the deficiencies are identified in section XIII and need to be clarified.

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II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	x		
Truthful and Accuracy Statement	x		
510(k) Summary or 510(k) Statement	x		
Standards Form			

The sponsor has provided the required certification of compliance for clinical trials (Form 3674). No clinical data has been referenced by this submission.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?	x		
Is the device sterile?		x	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	x		

The Zeltiq CLN1 Dermal Cooling Device consists of the following components:

- Applicators;
- Applicator Sleeves;
- Portable control unit containing the control and power system; and
- User Interface.

This device is a thermoelectric device that applies a user selected treatment profile in a controlled manner to a treatment site. It includes design enhancements to the predicate, Juniper CLN1 Dermal Cooling Device (K072152), as follows:

- An alternate vacuum applicator design. It includes the use of a vacuum to provide the massage feature. The vacuum applicator also draws tissue into the applicator during the cooling treatment.
- Inclusion of a (b)(4), (b)(5) for use with the coupling gel.
- Hardware modification to include a transmitter system for support of an accessory pager.
- Software upgrades to include the enhancements to the user interface.

The Zeltiq CLN1 Cooling Device, including the applicators and disposable sleeves, are sold non-sterile. Cleaning instruction is included in the Direction for Use: Zeltiq CLN1 Dermal Cooling Device. However, the cleaning instruction has not been included in the Direction for Use: Zeltiq Aethetics Vacuum Applicator Single Patient Use Sleeve.

III. Indications for Use

The Zeltiq CLN1 Cooling Device is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that include minor local discomfort. The Zeltiq CLN1 Cooling Device can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the relief of minor muscle aches, pain, and spasm and for the improvement in local circulation and in the temporary reduction in the appearance of cellulite.

The Zeltiq Coupling Gels facilitate thermal contact of the Zeltiq CLN1 Dermal Cooling Device with a patient's skin by mitigating minor variances in device-to-skin contact.

This indication statement is the same as that of the predicate, Juniper CLN1 Dermal Cooling Device (K072152). No change in the intended use also.

IV. Predicate Device Comparison

The sponsor has proposed the following predicates: Juniper CLN1 Dermal Cooling Device (K072152), MediSeb ElfCare thermal therapy device (K023231) for the intended use and mechanism of action; Cynosure Triactive Therapeutic massager (K030876) for the massager; and Spacelabs Ultraview Waveform Pager System (K992749) for the pager.

The sponsor has conducted the substantial equivalence comparison with these predicates. However, the vacuum feature of the pulsatile message and the wireless feature of the transmitter/pager have not been compared adequately.

V. Labeling

The sponsor has provided the package labels and Directions for Use for the following:

- Zeltiq CLN1 Dermal Cooling Device
- Zeltiq Aesthetics Vacuum Applicator Single Patient Use Sleeve

However, the information regarding to the paging system has not been included.

VI. Sterilization/Shelf Life/Reuse

The Zeltiq CLN1 Cooling Device, including the applicators and disposable sleeves, are sold non-sterile. Since the patient contact of the device is limited to the intact skin, this device is categorized as a non-critical patient contact device. According to FDA guidelines (http://www.fda.gov/cdrh/ode/198.pdf), the device will need to be thoroughly cleaned prior to use.
However, the sponsor has not addressed this issue regarding how to ensure or maintain the applicators and disposable sleeves clean prior to application.

VII. Biocompatibility

According to the sponsor, the only new patient contacting materials introduced in this design upgrade are (b)(4), (b)(5) (b)(4), (b)(5) (b)(4), (b)(5) (b)(4), (b)(5) (b)(4), (b)(5) (b)(4), (b)(5) (b)(4), (b)(5) (b)(4), (b)(5)
The sponsor also stated that the (b)(4), (b)(5) (b)(4), (b)(5) is currently marketed as a Class I medical device as an orthopedic accessory for casting (b)(4), (b)(5) (b)(4), (b)(5)

VIII. Software

Version: Rev. 08, Jan 11, 2008		
Level of Concern: Moderate		
	Yes	**No**
Software description: (Attachment 18-1)	x	
Device Hazard Analysis: (Attachments 18-2 and 18-3)	x	

Software Requirements Specifications: (Attachment 18-4)	x
Architecture Design Chart: (Attachment 18-1)	x
Design Specifications: (Attachment 18-1)	x
Traceability Analysis/Matrix: (Attachment 18-5)	x
Development: (Attachment 18-7)	x
Verification & Validation Testing: (Attachments 18-5 and 18-6)	x
Revision level history: (page 103)	x
Unresolved anomalies: (Section 8, Attachment 18-5)	x

The changes in the software from that of the predicate, Juniper CLN1 Dermal Cooling Device (K072152) include the following:

- Monitoring and feedback on the quality of the contact between the applicator and the skin prior to and during treatment;
- Monitoring and feedback on the detection of a freeze event during treatment including automatic shut off the device if a freeze event is detected; and
- Use of an optional pager that notifies the user of device status during treatment such as when the treatment is complete or if a system error occurs.

VIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The sponsor stated that the following electromagnetic and electrical safety testing is being conducted:
(b)(4), (b)(5)

(b)(4), (b)(5)

IX. Performance Testing – Bench

The sponsor has conducted the verification tests for the vacuum applicator and the disposable sleeves. Test results are provided (Attachments 20-1 and 20-2).

X. Performance Testing – Animal

XI. Performance Testing – Clinical

XII. Substantial Equivalence Discussion

	Yes	No	
1. Is Product A Device	x		If **NO** = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	x		If **NO** = Stop, see 510(k) staff
3. Same Indication Statement?	x		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
5. Same Technological Characteristics?			If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?			If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification 510kProgram/0_4147/FLOWCHART 510K DECISION.PDF for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. Explain how the new indication differs from the predicate device's indication:
   Please see section III and IV

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XIII. Deficiencies

1) Substantial Equivalence

(b)(4), (b)(5)

(b)(4), (b)(5)

b. Please revise the Substantial Equivalence tables to include detailed information of each category and identify relevant similarities and differences.
c. Please provide additional predicate(s) for some of the different features, or
d. Please provide data and/or rationale to justify that the differences do not adversely affect the safety and effectiveness of your device.

2) Vacuum Applicator

You indicate that an alternate vacuum applicator with the massage feature is included in this device. However, the information you provided for the vacuum applicator is not adequate.

a. Please describe in detail the functions and features of the vacuum applicator.
b. (b)(4), (b)(5) (b)(4), (b)(5)
c. Please discuss the safety features incorporated with the vacuum applicator.
d. Please provide a predicate for applying vacuum together with warm or cold massage; or
e. Please provide data and/or justification to demonstrate the safe use of vacuum applicator during warm or cold massage.

3) Paging System

You indicate that an optional paging system has been added to provide a secondary system to notify staff of system status. However, the information you provided for this paging system is not adequate.

a. Please describe in detail the components, functions and features of the paging system.
b. Please provide an overall hardware configuration diagram that includes this optional paging system.
c. Please include in your Software Architecture Design Chart (page 110) how the paging system will interface with the rest of the software system.
d. Please indicate whether the wireless communication is used between the transmitter and the pager.
e. Please include in your Direction for Use a section related to the paging system.

4) Wireless Technology

If wireless technology is used in your paging system, please address the following issues:

a. How users will interact with the system.
b. For wireless devices that use computer programs ("software"), the program's ability to handle the device responses and/or failures under EMI conditions
c. All functions that the wireless device will perform, and all safety-related requirements, specifications, features, and functions that will be implemented wirelessly
d. Wireless protocol specification name or designation (e.g., WMTS, IEEE 802.11b) for all wireless technologies incorporated into the device.
e. Wireless transmitter/receiver parameters such as operating frequency, output power, etc.
f. All coexistence, data integrity (e.g., data throughput, latency) and security features and performance requirements that the wireless system will meet.
g. Data security features to prevent unauthorized access to data or networks

5) Electrical Safety Test

In Section 19, Electromagnetic Compatibility and Electrical Safety, you indicate that the following electromagnetic and electrical safety testing is being conducted: Dielectric Strength (IEC/UL 60601-1),

Leakage Current (IEC/UL 60601-1), Emission of Electromagnetic Radiation (IEC/UL 60601-1), and Immunity to ESD (IEC/UL 60601-1).
Please confirm that

a. your device will be tested in compliance with the latest version of the IEC/UL 60601-1; and
b. the equipment under test (EUT) will include the paging system with transmitter and pager.

6) Cleaning Instruction
In Section 16, Sterilization & Shelf Life, you indicate that the applicators and disposable sleeves are not sold sterile. However, in your Direction for Use: Zeltiq Aethetics Vacuum Applicator Single Patient Use Sleeve, you did not address and/or provide instructions how to keep the sleeves and (b)(4), (b)(5) clean prior to use. Please clarify and revise your labeling accordingly.

7) Zeltiq Coupling Gel
You indicate in the labeling that Zeltiq Coupling Gel is applied to the patient prior to use of the system. However, you have not provided any information regarding to the Zeltiq Coupling Gel.

a. Please compare the Zeltiq Coupling Gel with (b)(4), (b)(5) in the predicate, Juniper CLN1 Dermal Cooling Device (K072152). If they are different,
b. Please provide detailed information of the Zeltiq Coupling Gel, including the manufacturing process, common and/or trade names of each chemical, etc..
c. Please provide predicate(s) for this Zeltiq Coupling Gel, or
d. Please provide data to demonstrate the safety and efficacy of the Zeltiq Coupling Gel.

XIV. Contact History

A telephone conversation with the sponsor (Donald V Johnson) followed up by an e-mail on 2/27/2008 asking for additional information.

XV. Recommendation

I recommend that this submission be placed on hold pending receipt of the response to the above questions.

Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Instrument, Surgical, Powered
Regulatory Class: Class II
Product Code: GEX
Additional Product Code: ILO, ISA

Long Chen
Lead Reviewer, GSDB/DGRND

2/27/08
Date

I concur with AI.

Neil Ogden
Branch Chief, GSDB/DGRND

2/28/08
Date

Chen, Long H

From: Chen, Long H
Sent: Wednesday, February 27, 2008 11:33 AM
To: 'djohnson@zeltiq.com'
Subject: 510(k) submission - Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118)

Attachments: k080118_email.1.doc

Don,

As discussed, I have enclosed a copy of the additional information request for the subject 510 (k) submission. Feel free to contact me for any further clarification.

k080118_em
l.1.doc (81 KE

Long
Long Chen, Ph.D.
(240)276-3628
GSDB/DGRND/ODE/FDA
long.chen@fda.hhs.gov

February 27, 2008

Mr. Donald V Johnson
VP Operations, Regulatory, & Quality Affairs
Zeltiq Aesthetics, Pleasanton, CA
Ph#: (925)-474-2509
Fax#: (925)-474-2599
e-mail: djohnson@zeltiq.com

Re: 510(k) submission - Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118)

Dear Mr. Johnson,

In reviewing the subject submission, we have the following additional questions that need to be clarified to facilitate our review process:

1) Substantial Equivalence

(b)(4), (b)(5)

(b)(4), (b)(5)

b. Please revise the Substantial Equivalence tables to include detailed information of each category and identify relevant similarities and differences.
c. Please provide additional predicate(s) for some of the different features, or
d. Please provide data and/or rationale to justify that the differences do not adversely affect the safety and effectiveness of your device.

2) Vacuum Applicator

You indicate that an alternate vacuum applicator with the massage feature is included in this device. However, the information you provided for the vacuum applicator is not adequate.

a. Please describe in detail the functions and features of the vacuum applicator.
b. (b)(4), (b)(5) (b)(4), (b)(5)
c. Please discuss the safety features incorporated with the vacuum applicator.
d. Please provide a predicate for applying vacuum together with warm or cold massage; or
e. Please provide data and/or justification to demonstrate the safe use of vacuum applicator during warm or cold massage.

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3) Paging System

You indicate that an optional paging system has been added to provide a secondary system to notify staff of system status. However, the information you provided for this paging system is not adequate.

a. Please describe in detail the components, functions and features of the paging system.
b. Please provide an overall hardware configuration diagram that includes this optional paging system.
c. Please include in your Software Architecture Design Chart (page 110) how the paging system will interface with the rest of the software system.
d. Please indicate whether the wireless communication is used between the transmitter and the pager.
e. Please include in your Direction for Use a section related to the paging system.

4) Wireless Technology

If wireless technology is used in your paging system, please address the following issues:

a. How users will interact with the system.
b. For wireless devices that use computer programs ("software"), the program's ability to handle the device responses and/or failures under EMI conditions
c. All functions that the wireless device will perform, and all safety-related requirements, specifications, features, and functions that will be implemented wirelessly
d. Wireless protocol specification name or designation (e.g., WMTS, IEEE 802.11b) for all wireless technologies incorporated into the device.
e. Wireless transmitter/receiver parameters such as operating frequency, output power, etc.
f. All coexistence, data integrity (e.g., data throughput, latency) and security features and performance requirements that the wireless system will meet.
g. Data security features to prevent unauthorized access to data or networks

5) Electrical Safety Test

In Section 19, Electromagnetic Compatibility and Electrical Safety, you indicate that the following electromagnetic and electrical safety testing is being conducted: (b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

6) Cleaning Instruction

In Section 16, Sterilization & Shelf Life, you indicate that the applicators and disposable sleeves are not sold sterile. However, in your Direction for Use: Zeltiq Aethetics Vacuum Applicator Single Patient Use Sleeve, you did not address and/or provide instructions

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how to keep the sleeves and (b)(4), (b)(5) clean prior to use. Please clarify and revise your labeling accordingly.

7) Zeltiq Coupling Gel

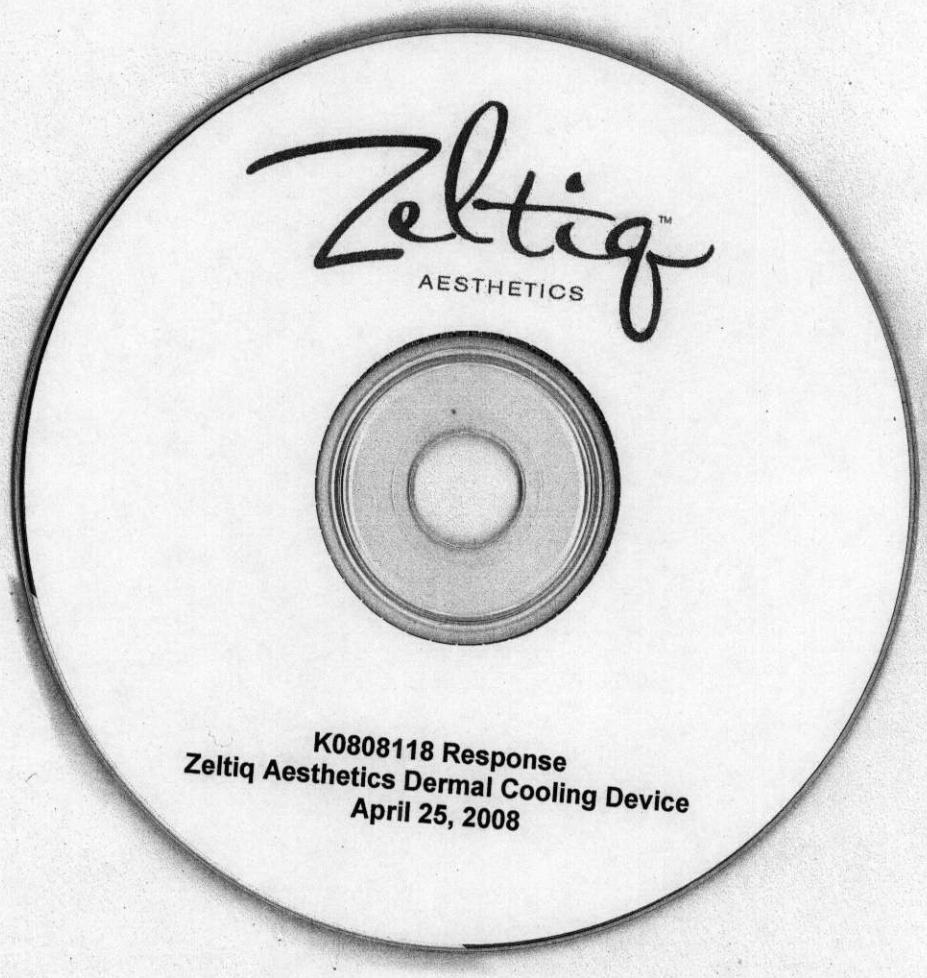
You indicate in the labeling that Zeltiq Coupling Gel is applied to the patient prior to use of the system. However, you have not provided any information regarding to the Zeltiq Coupling Gel.

a. Please compare the Zeltiq Coupling Gel with (b)(4), (b)(5) in the predicate, Juniper CLN1 Dermal Cooling Device (K072152). If they are different,
b. Please provide detailed information of the Zeltiq Coupling Gel, including the manufacturing process, common and/or trade names of each chemical, etc..
c. Please provide predicate(s) for this Zeltiq Coupling Gel, or
d. Please provide data to demonstrate the safety and efficacy of the Zeltiq Coupling Gel.

The subject submission will be placed on hold pending your response with the requested information. If you need more than 30 days to provide a full and complete response, you should submit a request for an extension of time to Document Mail Center (HFZ 401). For further information on how to apply for an extension and for general 510(k) information, please visit the FDA Website at:
http://www.fda.gov/cdrh/devadvice/31435.html#link_6

Sincerely,

Long Chen, Ph.D.
Chemical Engineer
Phone#: (240)276-3600, Fax#: (240)276-3733
General and Surgical Devices Branch
Division of General, Restorative and Neurological Devices
FDA/ODE


Zeltiq™
AESTHETICS
K0808118 Response
Zeltiq Aesthetics Dermal Cooling Device
April 25, 2008

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 14, 2008

ZELTIQ AESTHETICS
4698 WILLOW ROAD
PLEASANTON, CA 94588
ATTN: DONALD V. JOHNSON

510(k) Number: K080118
Product: ZELTIQ AESTHETICS CLN1 DERMAL COOLING DEVICE

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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Zeltiq
AESTHETICS

K080118 Response
Zeltiq Aesthetics Dermal Cooling Device
February 25, 2008

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K080118 K'

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
3/12/2008	MD6031965-956733	K080118

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☑ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☑ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Zeltiq Aesthetics	Establishment Registration Number *(if known)*:
Division Name *(if applicable)*:	Phone Number *(including area code)*: ((b)(4) (b)(4)
Street Address: 4698 Willow Road	FAX Number *(including area code)*: ((b)(4) (b)(4)
City: Pleasanton	State / Province: CA; ZIP/Postal Code: 94588; Country: USA
Contact Name: Donald V. Johnson	
Contact Title: Vice President, Operations, Regulatory, and Quality Affairs	Contact E-mail Address: (b)(4) (b)(4)

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name:	
Division Name *(if applicable)*:	Phone Number *(including area code)*: ( )
Street Address:	FAX Number *(including area code)*: ( )
City:	State / Province: ; ZIP/Postal Code: ; Country:
Contact Name:	
Contact Title:	Contact E-mail Address:

FORM FDA 3514 (9/07)

PAGE 1 OF 5 PAGES

PSC Graphics: (301) 443-1090 EF

K18

SECTION D1 — REASON FOR APPLICATION PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software/Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

☑ Other Reason *(specify)*:

Response to questions regarding K080118, in letter from FDA dated February 27, 2008.

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GEX	2	IOL	3	ISA	4	MSX
5	NUV	6	IRO	7		8	

Summary of, or statement concerning, safety and effectiveness information

- ☐ 510 (k) summary attached
- ☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K072152	1	CLN1 Dermal Cooling Device	1	Zeltiq Aesthetics, Inc
2	K030876	2	Cynosure Triactive Therapeutic Massager	2	Cynosure, Inc
3	K023231	3	Elfcare	3	MediSeb
4	K992749	4	Ultraview Waveform Pager System	4	Spacelabs Medical, Inc
5	K070092	5	Velasmooth	5	Syneron Medical, Ltd
6	K990445	6	Therapeutic Massager	6	LPG USA

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

	Trade or Proprietary or Model Name for This Device		Model Number
1	Zeltiq Aesthetics CLN1 Dermal Cooling Device	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K072152	2 K063715	3 K060407	4	5	6
7	8	9	10	11	12

Data Included In Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
ILO, GEX, ISA	890.5720, 878.4810, 890.5660	☐ Class I ☑ Class II ☐ Class III ☐ Unclassified

Classification Panel

Indications *(from labeling)*

The Zeltiq CLN1 Dermal Cooling Device is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq CLN1 Dermal Cooling Device can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and / or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the relief of minor muscle aches, pain, and spasm and for the improvement in local circulation and temporary reduction in the appearance of cellulite. The Zeltiq Coupling Gels facilitate thermal contact of the Zeltiq CLN1 Dermal

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)* K080118

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number		☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name			Establishment Registration Number		
Division Name *(if applicable)*			Phone Number *(including area code)* ( )		
Street Address			FAX Number *(including area code)* ( )		
City			State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title			Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number		☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name			Establishment Registration Number		
Division Name *(if applicable)*			Phone Number *(including area code)* ( )		
Street Address			FAX Number *(including area code)* ( )		
City			State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title			Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number		☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name			Establishment Registration Number		
Division Name *(if applicable)*			Phone Number *(including area code)* ( )		
Street Address			FAX Number *(including area code)* ( )		
City			State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title			Contact E-mail Address	

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SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

FORM FDA 3514 (9/07) **PAGE 5 OF 5 PAGES**

Zeltiq

FDA CDRH DMC
MAR 13 2008

March 11, 2008

Document Mail Center
510(k) Document Mail Center (HFZ-401)
Food and Drug Administration
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD 20850

Re: 510(k) submission - Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118)

Dear Dr. Chen:

The following is in response to additional questions presented by FDA in a letter dated February 27, 2008 regarding the subject submission. Each question presented by FDA is listed in italics, followed by the response from Zeltiq Aesthetics.

1) *Substantial Equivalence*

(b)(4)

(b)(4)

Table 1. Substantial Equivalence Matrix for the Zeltiq CLN1 Dermal Cooling Device – Vacuum Applicator

Element	Zeltiq CLN 1 Dermal Cooling Device (subject of this submission)	Juniper CLN1 Dermal Cooling Device K072152	Cynosure Triactive Therapeutic Massage System K030876	LPG USA K990445	Syneron Velasmooth K070092
Principle of Operation					
Vacuum function	(b)(4) (b)(4)	NA	Create skin fold	Create skin fold	Create skin fold
Massage (e.g., mechanical manipulation)		Vibration	Pulsatile vacuum	Pulsatile vacuum and rollers	Pulsatile vacuum and/or massage
Massage with simultaneous heating		Yes, optional	Yes	No	Yes
Massage/cooling		Yes, possible contact cooling at skin. Precaution in DFU: "The effects of simultaneous use of massage and cold with the Zeltiq CLN1 Dermal Cooling Device have not been established, and such simultaneous use should be avoided."	Yes, simultaneous superficial skin cooling	No	Yes, contact cooling on skin
Design Features					
Console with electrically powered vacuum pump	Yes	NA	Yes	Yes	Yes
Pulsatile vacuum	Yes	Yes	Yes	Yes	Yes
Suction power	(b)(4) (b)(4) (b)(4)	(b)(4) (b)(4)	Unknown	37-375 mm Hg (50 -500 mBar Hg)	150 mm Hg (b)(4) (b)(4)
Frequency	1-10 Hz	NA	0.1 -5 Hz	0.41 – 19.23 Hz	Unknown
Cycle rate	50%	NA	10-90%	10-90%	Unknown
Power Source	120 VAC/ 60 Hz	120 VAC/ 60 Hz	120 VAC/ 60 Hz	120 VAC/ 60 Hz	120 VAC/60 Hz
Sterility	Non sterile	Non sterile	Non sterile	Non sterile	Non sterile
Reusable	Yes	Yes	Yes	Yes	Yes

Additional information has been added to the substantial equivalence comparison table for the pager to include the transmission technology and additional features. See Table 2.

b. *Please revise the Substantial Equivalence tables to include detailed information of each category and identify relevant similarities and differences.*

As discussed in the response to Question 1a above, a separate substantial equivalence comparison table for the vacuum applicator has been included with additional information on technological characteristics and features. Additional information also has been included in the substantial equivalence table for the pager. See Tables 1 and 2.

c. *Please provide additional predicate(s) for some of the different features, or*

(b)(4)

(b)(4)

d. *Please provide data and/or rationale to justify that the differences do not adversely affect the safety and effectiveness of your device.*

Not applicable; additional predicates were provided in response to Question 1c above.

Table 2. Substantial Equivalence Matrix for the Zeltiq CLN1 Paging Device

Element	Zeltiq CLN 1 Dermal Cooling Device (subject of this submission)	Spacelabs Ultraview Waveform Pager System (K992749)
Indications for Use	To provide a secondary means of notification and display of system status (e.g., procedure completion, system error) to mobile health care providers	• …to provide a secondary means of notification and display of patient alarm information to mobile health care providers • …for use in real-time monitoring of routine patient status and alarm events
Principle of Operation		
Server	The control unit acts as the server that collects and formats (b)(4) (b)(4) (b)(4) (b)(4) (b)(4)	A server collects and formats (b)(4) (b)(4)
Transmitter	(b)(4) (b)(4)	Any Flex-Binary paging transmitter that meets site requirement (and frequency requirement)
Transmission Technology	Wireless	Wireless
Transmission Frequency	UHF frequency (420 – 470 MHz) with synthesized frequency and modulation	Protected 929-931 MHz paging band
Receiver (Pager)	Battery operated alphanumeric pager by (b)(4) (b)(4) that stores up to 99 messages.	Battery operated, alphanumeric pager by Motorola (CP1250) that stores up to 43 messages
Design Features		
Transmitter	Messages delivered "immediately"	Notification occurs within 4 to 8 seconds after an alarm event (for telemetry and hardwired patients)
Transmission Data	ASCII text messages; device status	Text messages and waveforms; patient data
Transmission Sequence	Forwarding mechanism	Forwarding mechanism
Security	None required; transmission is device status only, no patient data	Unknown
Receiver (Pager)	(b)(4) (b)(4)	7. Stores up to 43 messages 8. Displays up to 8 lines of text, zooms in to 4 lines for larger view. 9. Backlighting 10. User selectable alerts 11. Operates on a single AAA battery 12. Low battery indicator
Other Features		
Reusable	(b)(4)	Yes

2) *Vacuum Applicator*

You indicate that an alternate vacuum applicator with the massage feature is included in this device. However, the information you provided for the vacuum applicator is not adequate.

a. *Please describe in detail the functions and features of the vacuum applicator.*

(b)(4)

(b)(4)

b. (b)(4)

(b)(4)

(b)(4)

c. *Please discuss the safety features incorporated with the vacuum applicator.*

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

d. *Please provide a predicate for applying vacuum together with warm or cold massage; or*

Additional predicates for the use of vacuum together with warm or cold massage are included in response to Question 1c above.

e. *Please provide data and/or justification to demonstrate the safe use of vacuum applicator during warm or cold massage.*

Not applicable; additional predicates were provided in response to Question 1c above.

3) <u>Paging System</u>

You indicate that an optional paging system has been added to provide a secondary system to notify staff of system status. However, the information you provided for this paging system is not adequate.

a. *Please describe in detail the components, functions and features of the paging system.*

The following describes the components, functions and features of the paging system.

The paging system has the following components, as previously described in Section 13.4.2 on page 37 of the original 510(k):

- The control unit, which collects and formats (b)(4) (b)(4) (b)(4) (b)(4)
- A transmitter (b)(4) (b)(4) that is located in the control unit, receives input via a RS232 port and transmits messages via UHF frequency (b)(4) (b)(4) and
- An alphanumeric pager (b)(4) (b)(4) that receives messages from the transmitter.

The function of the paging system is to provide a secondary system to notify staff of system status: when a treatment session is cancelled, procedure completion or system error.

Further detail describing the components, functions and features is provided in DR-10051, CLN1 Software Design Description (Attachment 3).

b. Please provide an overall hardware configuration diagram that includes this optional paging system.

We have updated DR-10051, CLN1 Software Design Description, including Figure 1 (the Software Architecture Design chart on page 110 of the original submission) to include the optional pager system. Note that the Software Architecture Design chart includes hardware configuration.

This updated document has been provided in Attachment 3; the updated figure is provided below for your convenience, highlighting the addition of the pager and transmitter.

CLN1 Software Architecture

(b)(4)

(b)(4)

c. *Please include in your Software Architecture Design Chart (page 110) how the paging system will interface with the rest of the software system.*

Please see the response to Question 3b above and Attachment 3, DR-10051, CLN1 Software Design Description, which describes additional interactions between the paging system and the rest of the software system.

d. Please indicate whether the wireless communication is used between the transmitter and the pager.

Wireless communication is used between the transmitter and the pager; specific details are provided in the response to Question 4.

e. Please include in your Direction for Use a section related to the paging system.

The Directions for Use have been revised to include a section related to the paging system. Please see Section 2.5 of PL10691 Rev D, Zeltiq CLN1 Dermal Cooling Device Directions for Use, (Attachment 2). Note that for convenience, this section has been reproduced in the response to Question 4a below.

4) Wireless Technology

If wireless technology is used in your paging system, please address the following issues:

a. How users will interact with the system.

Section 2.5 of PL10691 Rev D, Zeltiq CLN1 Dermal Cooling Device Directions for Use, (Attachment 2) contains the following instructions for user interactions with the paging system:

(b)(4)

(b)(4)

1. (b)(4)

2. (b)(4)

3.

(b)(4)

4.

(b)(4)

5.

b. For wireless devices that use computer programs ("software"), the program's ability to handle the device responses and/or failures under EMI conditions.

The wireless device is external to our product software. Our software's ability to operate correctly under EMI conditions was validated during our systems-level EMI testing.

c. All functions that the wireless device will perform, and all safety-related requirements, specifications, features, and functions that will be implemented wirelessly.

Wireless functionality consists solely of (b)(4) (b)(4)
(b)(4)
(b)(4)
(b)(4)

d. Wireless protocol specification name or designation (e.g., WMTS, IEEE 802.11b) for all wireless technologies incorporated into the device.

ASCII text messages are sent to the paging transmitter through a USB to serial interface. Wireless messages are transmitted using an LRS proprietary FM encoding scheme.

e. *Wireless transmitter/receiver parameters such as operating frequency, output power, etc.*

The following table lists the wireless transmitter/receiver parameters.

	Operating Frequency	**Required Voltage**	**Output Power**	**Operating Range**
Transmitter	467.750MHz	110	1 Watt	~2 miles
Receiver	467.750MHz	One AAA Alkaline battery	N/A	~2 miles

f. *All coexistence, data integrity (e.g., data throughput, latency) and security features and performance requirements that the wireless system will meet.*

The data rate of the serial link to the pager transmitter is 9600 bps. The software checks that the pager transmitter does not return an error when sending an ASCII string, but there is no handshake with the page receiver.

There are no security features required. Because of the wireless link, there are no performance expectations that can be made of the pager (receiver may be powered off, out of range, or not physically proximal to the user). Empirical testing in our facility found the range to exceed 100 feet (the anticipated range of use with the Zeltiq system).

g. *Data security features to prevent unauthorized access to data or networks*

The onsite paging system is not connected to any network nor are there any data which require protection. The pager transmitter data does not include any patient information; the information is limited to device status.

5) <u>Electrical Safety Test</u>
In Section 19, Electromagnetic Compatibility and Electrical Safety, you indicate that the following electromagnetic and electrical safety testing is being conducted: Dielectric Strength (IEC/UL 60601-1), Leakage Current (IEC/UL 60601-1), Emission of Electromagnetic Radiation (IEC/UL 60601-1), and Immunity to ESD (IEC/UL 60601-1). Please confirm that

a. *your device will be tested in compliance with the latest version of the IEC/UL 60601-1; and*

The device testing will be tested in compliance with the latest version of the IEC/UL 60601-1, that is the 3rd addition, December 2005.

b. *the equipment under test (EUT) will include the paging system with transmitter and pager.*

The paging system will be tested as part of the device for compliance with the latest version of the IEC/UL 60601-1.

6) <u>Cleaning Instruction</u>

In Section 16, Sterilization & Shelf Life, you indicate that the applicators and disposable sleeves are not sold sterile. However, in your Direction for Use: Zeltiq Aesthetics Vacuum Applicator Single Patient Use Sleeve, you did not address and/or provide instructions how to keep the sleeves and (b)(4) (b)(4) *clean prior to use. Please clarify and revise your labeling accordingly.*

The sleeves and (b)(4) (b)(4) are provided in packaging in which they are intended to be stored until the time of use. They also are intended for a single use and are to be disposed after each procedure. Therefore, it is believed that there is no need for specific instructions regarding how the sleeves and (b)(4) (b)(4) are to be kept clean prior to use.

7) <u>Zeltiq Coupling Gel</u>

You indicate in the labeling that Zeltiq Coupling Gel is applied to the patient prior to use of the system. However, you have not provided any information regarding to the Zeltiq Coupling Gel.

a. *Please compare the Zeltiq Coupling Gel with* (b)(4) (b)(4) *in the predicate, Juniper CLN1 Dermal Cooling Device (K072152). If they are different,*
b. *Please provide detailed information of the Zeltiq Coupling Gel, including the manufacturing process, common and/or trade names of each chemical, etc..*
c. *Please provide predicate(s) for this Zeltiq Coupling Gel, or*
d. *Please provide data to demonstrate the safety and efficacy of the Zeltiq Coupling Gel.*

(b)(4)

(b)(4)

The following table is provided to facilitate your review of this submission and understanding of the name changes.

New Name	Old Name	Submission
Zeltiq Coupling Gel	Juniper Medical Coupling Gel	K063715
Zeltiq Coupling Gel (b)(4)	Juniper Coupling Gel (b)(4)	(b)(4) (b)(4)
Zeltiq Coupling Gel	Juniper Coupling Gel	

We trust that the additional information provides the clarification needed for completion of the review process for the subject submission. If there are any questions, or if additional information is required, however, please contact me at (b)(4) (b)(4) or by email at (b)(4) (b)(4)

Sincerely,

Donald V. Johnson
Vice President, Operations, Regulatory, and Quality Affairs
Zeltiq Aesthetics, Inc.

Enclosed:

Attachment 1: Additional Predicate Devices: LPG Therapeutic Massager and Syneron Velasmooth.

Attachment 2: PL10691-D Zeltiq CLN1 Dermal Cooling Device Directions for Use.

Attachment 3: DR10051-B CLN1 Sortware Design Description.

ATTACHMENT 1: ADDITIONAL PREDICATE DEVICES: LPG THERAPEUTIC MASSAGER AND SYNERON VELASMOOTH.

LIPOMASSAGE Technology, Independent Motorized Rollers

LPG IMR Technology
Lipomassage's principle is based upon two electronically controlled motorized rollers located in an airtight chamber. Working with aspiration, the unique, patented LPG Roll Heads -or Independent Motorized Rollers (IMR) --form a 'wave' that folds and unfolds the skin. The skinfoldis rolled at variable speeds, using forward or backward, diagonal or lateral maneuvers, according to the specific treatment objective.

The most recent generation CelluM6 Keymodulei50 technology features a redesigned treatment head' with speed and rotation differentialsand additional programs for greater depth of action and dramatically expanded applications.

Depending on the rotation direction and speed of the independent motorized rollers, the skin is drawn in numerous different folds -all of different shapes, depths and thicknesses. As this happens, sensors provide instant feedback and a user friendly menu control display acts as a biofeedback monitoring system, providing users with extremely accurate treatment data

Now with the Roll'inand the new and improved LPG protocols, Lipomassage by Endermologiedelivers more intensive deep tissue treatments for faster measurable results than ever before.

• Roll'in
Allows for a more slenderized and streamlined physique, making dense, excess fats available for elimination.

• Roll'out
Reconditions and structurally redensifiesdeep layers of loose, sagging skin that topical solutions are unable to tone, tighten or firm

• Roll'up
Reshapes figure flaws to help one attain the optimal physical aesthetic.

K990145

JAN 18 2000

510 (k) Summary

Applicant's Name: LPG USA

Applicant's Address: 3101 North Federal Highway (Suite (301)
Fort Lauderdale, FL 33306

Contact Person: Walter L. Wasserman

Phone Number/contact person: (954)568-5005
Fax Number/contact person: (954)568-6611

Address of manufacturing site: LPG Systems
Technoparc de la Plaine
30 Rue du Docteur Abel
BP 35-26902 Valence Cedex 9, France

Date Summary Prepared: January 18, 2000

This summary includes sections 2 through 8.

2. Device Name

- Therapeutic Massager (21 CFR 890.5660)
- Proprietary names – LPG Therapeutic Massager - Models - ES1
- Therapeutic Massager/Vibrator (21 CFR 890.5660 and 890.5975)
- Proprietary names - LPG Therapeutic Massager/ Vibrator – Models – Cellu M6; ES/M60; S6; and LPG Equine

3. Establishment registration number

1062948

4. Classification of device
- Class I
- Product codes – 89 ISA and 89 IRO
- Panel - Physical medicine

5. Performance standards
There are no performance standards established under section 514

6. Labeling

6.1
Indications for use
- Relieves minor muscle aches and pains
- Relieve muscle spasm
- Temporary improvement in local circulation
- Temporarily reduces the appearance of cellulite
- Relieves minor muscle aches and pains, relieves muscle spasm and temporarily improves local circulation during Burn rehabilitation

Contraindications
- Known sensitivity to the device
- Do not treat over open wounds
- Skin cancer in the treated area
- Do not treat HIV positive patients

Caution
Federal law restricts thus device for sale to or use under the order of a licensed physician

Precautions:

When treating patients for burn rehabilitation care should be taken to carefully follow the instruction manual and not to exceed suction levels that would be obviously uncomfortable for the patient.

6.2

510(k) Number K99045
Device Name: LPG Therapeutic Massager/Vibrator

Intended uses

- Relieves minor muscle aches and pains
- Relieve muscle spasm
- Temporarily Improve local circulation
- Temporarily reduces the appearance of cellulite
- Relieves minor muscle aches and pains, relieves muscle spasm and improves local circulation during Burn rehabilitation

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use _____ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

4 LPG USA Confidential

7. Substantial equivalence comparison

This product is substantially equivalent to a product already on the market LPG Therapeutic Massager (21 CFR 890.5660). The LPG technique involves a mobilization of the tissue accomplished with the LPG devices. All models with the exception of the ES1 and LPG Equine have both continuous and cyclic or pulsating modes of action. This pulsating function is equivalent to Therapeutic Vibrators (21 CFR 890.5975). And as such Substantial Equivalence is also claimed to the following legally marketed devices, which are also Class I.

- G5-GK1 - K850851
- VIBRATOUCH™ II K912383

Table of Comparison

Device	Indications	Design	Specifications
LPG Massager/Vibrator	Minor muscle pain Relieve muscle spasm; Temp. improvement in appearance of cellulite; Temp. increase of local circulation; Burn Rehab.	5 models 5 applicators 12 treatment heads 3 motorized heads	Ground current Leakage <50 micamp.
G5-GK1 Vibrator	Minor muscle pain	17 applicators 3 models hand held	12'x3'x3' - 3.8 lbs.; 0.25HP; 110V, 60 cycle <75 micamp. ground current leakage
VIBRATOUCH II	Minor muscle pain	2 speeds; Battery Power	not specified

Our objective is not to substantiate new claims but to prove that the exempt claims are appropriate for the burn victim and that the product is safe and effective for its general uses when used in burn rehabilitation.

8.

The LPG Technique:

The LPG technique involves mobilization of tissue accomplished with the LPG devices.
LPG stands for Louis Paul Guitay inventor of these therapeutic massagers.
LPG after a car accident that had left scars on his body was receiving treatments from a physical therapist using a tissue mobilization technique called Skin Fold Rolling. After a number of treatments, LPG noticed a difference in the Skin Fold Technique due to the practitioner performing the maneuvers or the time of the treatment. LPG had the idea to make the technique more consistent and replicable using vacuum power to lift the skin and make a fold that is mobilized by two motorized rollers.

The LPG devices:

Based on similar concepts, the LPG devices are intended for practitioners who work in specific fields but all are substantially equivalent devices:

- ES1 for Endermologie
- Cellu M6 for Endermologie and therapeutic applications
- S6 sport for sport applications, before, after exercise and rehabilitation after injuries
- ES/M60 for therapeutic applications and cosmetic applications on the face or on small area
- LPG Equine for animal treatment.

These devices are substantially equivalent to the ES1 therapeutic massager because the mode of operation and operating parameters and specifications are basically the same.

Each LPG device comprises a main console housing a vacuum pump and a computerized regulation system.
All of them contain treatment heads (from 5 to 12), that are designed to accommodate all parts of the body. ES1, Cellu M6, S6, LPG Equine devices have a main motorized head, the other device contain auxiliary heads (non-motorized) only. The equine device head is the largest in order to be able to be applied on the horse's body surface.
The suction power of all these machines range from 50mBar to 500mBar which is represented by a scale from 1 to 10; for a specific machine and application, the suction power must be cyclically interrupted to provide vibration to the skin which is another stimulation for the tissues.

The motorized head:

This patented head (*number 4,729,368 US*) contains more than 200 individual parts and contains two motorized rollers that move together and apart, at each end of the suction chamber. The two rollers are mobilized in rotation and in sliding back and forth. They provide, to the

head, the capability of creating a fold of skin and subcutaneous fat with a very efficient contact, which allows better mobilization. This is also enhanced by specific maneuvers.

To visualize the reaction of tissue in-vivo, some endoscopic views were recorded within the main head.

The auxiliary heads:

In addition to the main head, a set of auxiliary heads can be used with two non-motorized rollers on smaller parts of the body, particularly the face, the limbs, the neck, and all the specific area, which need treatment. These heads are called regarding the size of the rollers: 15, 30, 44 millimeters; the ES/M60 device contains a larger head with specific ergonomic features (i.e. handle on the top of the head) but the same design. Recently, LPG had added small springs at each end of the rollers to provide lateral mobilization of them during the treatment.

Rhythmicity or cyclic pulsation and mobilization:

For a specific machine and application (Cellu M6, S6, M60, and LPG Equine), the suction power is cyclically interrupted to provide vibration to the skin fold between the two rollers, which is another form of stimulation for tissues. Added to the device for the comfort of the patient, the cyclic suction power, according to scientific literature, provides additional effects to the tissue. Because of that, the therapeutic massager that includes vibration could be described as a form of therapeutic vibrator as well.

This cyclic pulsation feature is modulated by two variables:

- **Cycle rate**

The cycle rate regulates the proportion of time devoted to suction and rest. It is a ratio, the cycle rate ranges from 1 to 9, 1 for 10% suction versus 90% rest, 9 for 90% suction versus 10% rest, 5 for 50% suction versus 50% rest.

- **Frequency**

The frequency is the number of repetitions of one cycle per second. The frequency range from 0.41 to 19.23 Hz; these numbers appears on the screen as 0.0 for 0.41 Hz to 199 for 19.23 Hz.

In order to apply to the skin fold effective vibration, it is necessary to choose an adjustment with high frequency and low cycle rate or low frequency and high cycle rate. If the chosen adjustment is high frequency and high cycle rate, the skin fold is constantly lifted and the action is equivalent to the constant suction. If the chosen adjustment is low cycle rate and low frequency, the skin fold is mostly relaxed and therefore there will be less or no effectiveness.

This cyclic pulsation should not be considered as a single event but rather as repetitive stimulation that could produce harmonics (additional modes of stimulation). Thus the specific adjustments of the machine are less significant than it appears because of the harmonic summation.

The literature contains many citations showing the effectiveness of vibration of various frequencies; (i.e. has been shown on microcirculation, on pain and on muscle spasm).

LPG has investigated this area in one studies:

Doctor Gavroy compared treatment on burn victim with LPG and rhythmicity and LPG without rhythmicity.

History of the LPG Technique:

A number of French medical doctors advised Louis Paul Guitay about using the device to treat low back pain, a condition very frequently associated with some types of change in the skin and subcutaneous fat. This is called secondary cellulitis on the back or around the pelvic bone (iliac crest). They also recommended treating neck ache with huge fatty localization around C7 (which is called buffalo hump).

Therapist successfully using the CelluM6 device on female patients suffering low back pain, also noticed that their patients were showing an improvement in the appearance of their cellulite or commonly called orange peel skin.

Results on the appearance of cellulite were so significant that LPG decided to market the product for this effect. The device was then sold for two applications (cosmetic and therapeutic).

When LPG decided to sale the LPG therapeutic Massager for its effect on cellulite, a specific methodology based on physiological and pathological data was designed:

- **Global methodology** involving torso massage designed to improve circulation at the pelvic and abdominal level
- **Tissue mobilization** with specific maneuvers acting upon the venous system, lymphatic system, blood system which are sensitive to surrounding tissue movements
- **Adjusted suction power** to the sensitivity and the thickness of the tissues
- An average of **fourteen sessions** (two sessions per week) without interruption, during **35** to **45** minutes each.

Because this methodology represents a specific and innovative way to tackle this skin condition, the company decided to invent a name for it: the word "**Endermologie**" was chosen and became a trademark.

Thus, it was evident that Endermologie could be only done with the LPG Therapeutic Massagers because of the specificity of the patented heads.

To date the LPG devices such as therapeutic massagers have got the exempted claims:

Relieves minor muscles aches and pain

Temporarily increases local blood circulation

Relaxes muscles spasm

Since, April 1998, the LPG therapeutic massager has been permitted the claim:

Temporary reduction in the appearance of cellulite.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2000

Mr. Frederic Barthe
Vice President
LPG USA, Inc.
3101 North Federal Highway
Suite 301
Fort Lauderdale, Florida 33306

Re: K990445
Trade Name: LPG Therapeutic Massager Vibrator
Regulatory Class: I
Product Code: ISA
Dated: October 18, 1999
Received: October 20, 1999

Dear Mr. Barthe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

6.2

510(k) Number K990445
Device Name: LPG Therapeutic Massager/Vibrator

Intended uses

- Relieves minor muscles aches and pains
- Relieve muscle spasm
- Temporarily improves local blood circulation
- Relieves minor muscle aches and pains, relieves pains, relieves muscle spasm and improves local circulation during burn rehabilitation

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use X OR Over-the-Counter-Use
(Per 21 CFR 901.109

(Optional Format 1-2-96) _____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990445

VelaSmooth™

About VelaSmooth

- What is VelaSmooth?
- How it works
- Treatment areas
- Benefits
- Improve your results
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- What is elōs technology?

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Getting started
Praise
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elōs Technology

elōs is the first and only technology that simultaneously harnesses the power of bi-polar radio frequency (RF) and optical energy. Developed by Intense Pulse Light inventor/patent-holder, Dr. Shimon Eckhouse and master physicist, Dr. Michael Kreindel. This revolutionary technology platform effectively overcomes the safety and procedural limitations of intense pulse light (IPL) and conventional lasers.

The elōs Difference

- Radio Frequency is a highly controllable energy heat source, works synergistically with optical energy
- Enables the use of light energy at a level that is safe for all skin types
- No additional risk to the epidermis
- Precisely targets areas "preheated" by optical energy
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http://www.syneron.com/Solutions/Physicians/Products/Specs/VelaSmooth_Spec.html

SYNERON PRODUCTS

VelaSmooth Specifications

VelaSmooth System Specifications

Infrared power	Up to 20w
RF power	Up to 20w
Light spectrum	700-2000nm
Vacuum	Pulsed
Treated area	40 x 40mm
Platform weight	~60 lbs (35kg)
Platform size	31" x 20" x 14" (80 x 50 x 35 cm)

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neron.com/Solutions/Physicians/Products/velasmooth.html

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VelaSmooth™: The first nonsurgical, FDA-cleared medical solution for cellulite

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Powered by the revolutionary elōs™ Technology, VelaSmooth is the first and leading FDA-cleared non-invasive medical solution for the reduction of cellulite. It is estimated that 80% of all women over the age of 20 have cellulite, and VelaSmooth is the first device of its kind to allow you to safely treat it. Give your patients the smooth-looking skin they desire with zero downtime.

The New **VelaSmooth Contour Applicator** delivers deeper, dense heating to smaller target treatment areas. When used in conjunction with the larger, VelaSmooth Body Applicator, you can produce more pronounced results, faster.

A Proven Solution for Multiple Treatment Areas: Posterior Thigh • Buttocks • Outer Thigh & Hip • Anterior Thigh • Inner Thigh • Upper Arm • Neck • Saddlebags • Love Handles • Abdomen

"I am very pleased with the VelaSmooth and the results that my patients are seeing. They report a boost in self-confidence and look forward to their VelaSmooth appointments. Excellent results!"

~ Cindy Ann Eckstein, CEO, Smooth Body Laser Center

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You and VelaSmooth - a beautiful opportunity

- Safe, effective treatment of cellulite
- National brand-recognition from consumer focused vela smooth website, extensive media campaign and media coverage.
- Large market — an estimated 80% of women over age 20 have cellulite
- Clinically proven results with zero downtime
- Easy to use — Low maintenance, ergonomic applicator, portable system

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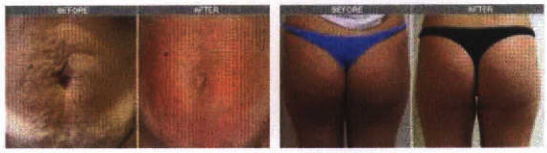

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- Uses significantly less energy than conventional lasers and IPLs
- elōs means better results, patient comfort, and patient satisfaction

ELŌS EXCELLENT PRACTICE ROI

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- Practice Support from national media campaigns to individualized marketing plans and clinical training
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VelaSmooth SYSTEM SPECIFICATIONS

Infrared Power	Up to 20 W
RF Power	Up to 20 W
Light Spectrum	700 – 2000 nm
Vacuum	Pulsed
Treated Area Body Applicator Contour Applicator	 40 x 40 mm 30 x 30 mm
Skin Impedance Control	Online
Platform Weight	60 lbs (27 kg)
Platform Size	31 x 20 x 14" (80 x 50 x 35 cm)
Electrical Requirements	Standard 110 VAC (230 VAC)

Syneron™ has the Proof that matters most to your Success.

Proven Technology.

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Proven, Documented Clinical Efficacy.

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View our growing list of clinical papers and treatment photos.
Get detailed product specifications. Learn how to optimize
your practice's success with the VelaSmooth system.

Visit us online at www.syneron.com

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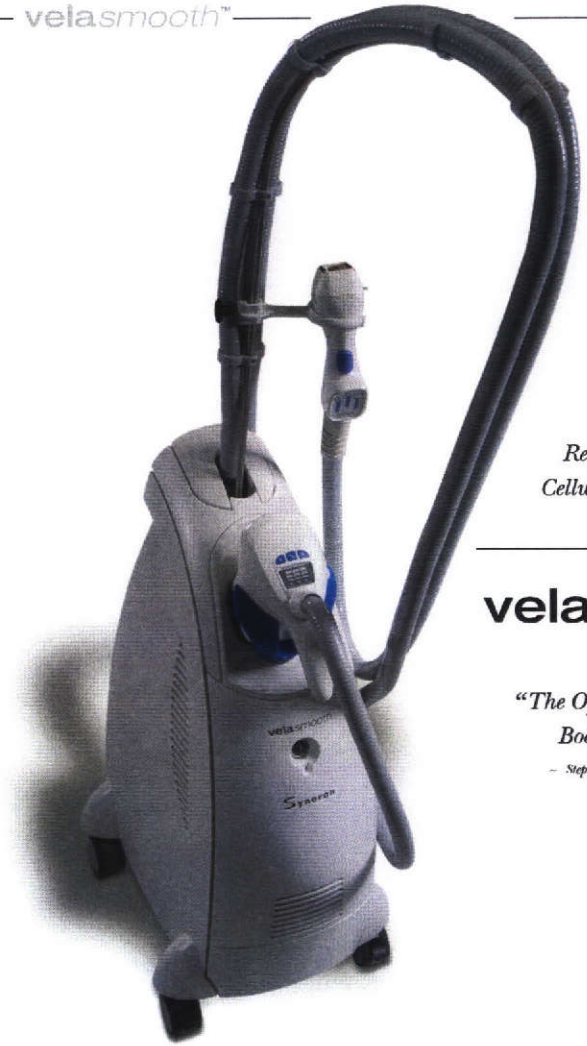
Tel: +972 4 909-6200

Syneron™
Superior Technology, Ultimate Customer Care

velasmooth™

Body Treatment



Revolutionary
Cellulite Treatment

velasmooth™

"The Optimal Contoured Body Solution"

– Stephen Mulholland, M.D.

Syneron™
Superior Technology, Ultimate Customer Care

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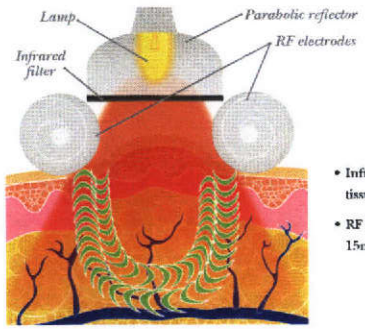
REVOLUTIONARY
CELLULITE AND BODY CONTOURING RESULTING FROM CELLULITE TREATMENT.

While there are many heat and massage systems available claiming to treat cellulite, **velasmooth**™ is the first medical device clinically proven for the effective treatment of cellulite.

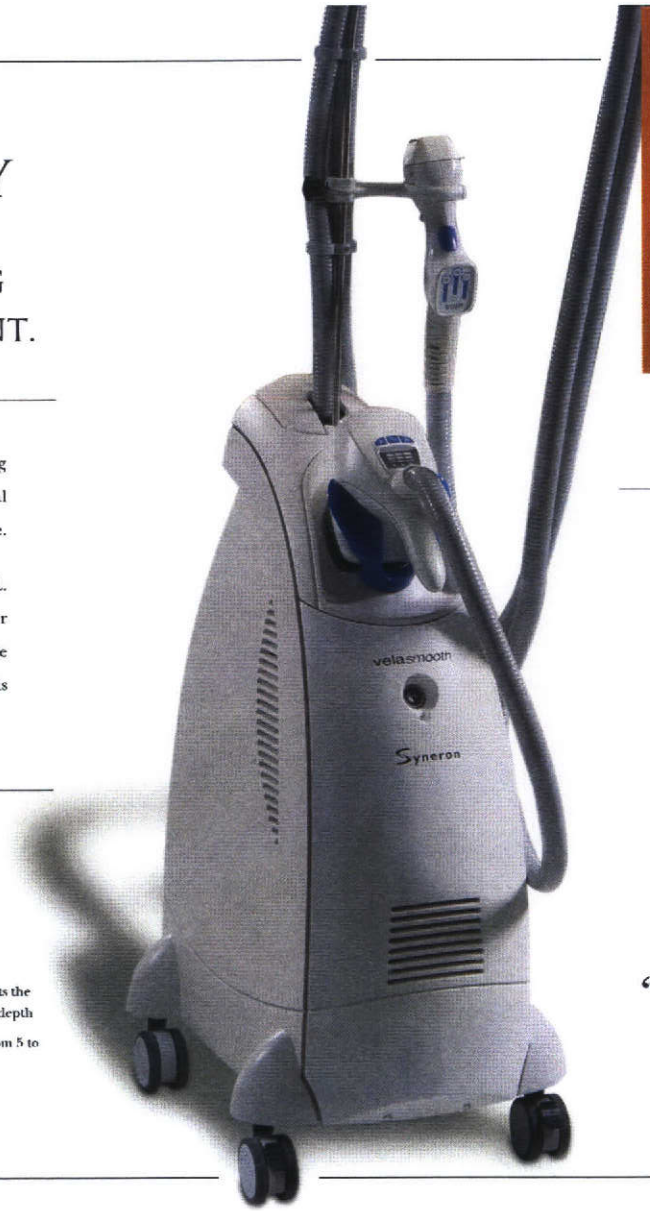
HUGE DEMAND, PROVEN REVENUE POTENTIAL.

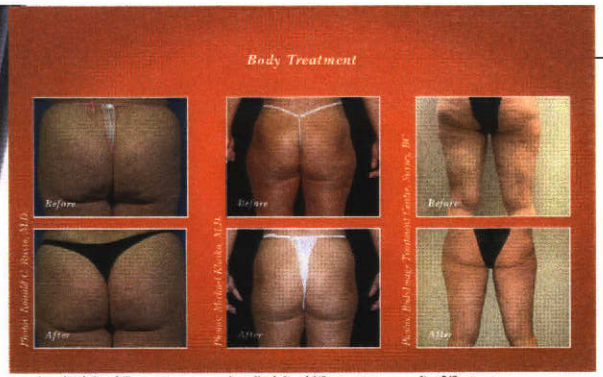
It is estimated that 80% of women over age 20 have cellulite. Meet the incredible demand for effective treatment with this safe, non-invasive solution.

THE elōs™ TECHNOLOGY ADVANTAGE.



- Infrared light heats the tissue up to 5mm depth
- RF heats tissue from 5 to 15mm depth





Immediately Post 8 Treatments. *Immediately Post 16 Treatments.* *Post 8 Treatments.*

The EXTRAORDINARY SCIENCE *of* VELASMOOTH.

VelaSmooth features the revolutionary elōs combination of Bi-Polar Radio Frequency *(RF)*, Infrared Light energies, plus negative pressure and tissue manipulation.

Vacuum and specially designed rollers manipulate and smooth out the skin to facilitate safe and efficient energy delivery.

The synergistic combination of infrared and conducted RF energies increase oxygen intracellular diffusion by heating the skin.

The net result increases the metabolism of stored energy (lipolysis) thereby reducing or shrinking the size of the actual fat chamber.

The result: A smoother appearance of the skin's surface.

"I am very pleased with the VelaSmooth and the results that my patients are seeing. Excellent results!"

– John Pletincks, M.D.
The Vein Clinic

The new VelaSmooth Contour Applicator™ delivers deeper, dense heating to smaller target treatment areas. This helps produce more pronounced results, faster.

A PROVEN SOLUTION *for* MULTIPLE TREATMENT AREAS

Posterior Thighs • Buttocks
Outer Thighs & Hips
Anterior Thighs • Inner Thighs
Upper Arms • Neck
Saddlebags • Love Handles
Abdomen

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ATTACHMENT 2: PL10691-D ZELTIQ CLN1 DERMAL COOLING DEVICE DIRECTIONS FOR USE.

Zeltiq

Zeltiq CLN1 Dermal Cooling Device
Directions for Use

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Zeltiq Aesthetics, Inc.
4698 Willow Road
Pleasanton, CA 94588
(925) 474-2500
www.zeltiq.com

Authorized Representative
Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

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ATTACHMENT 3: DR10051-B CLN1 SORTWARE DESIGN DESCRIPTION.

Author / Revised by:	Approved By:	Date:
(b)(4) (b)(4)	(b)(4) (b)(4)	6 March, 2008
Project: CLN1		
Title: CLN1 Description, Software Design		

(b)(4)

(b)(4)

Revision History

(b)(4)

(b)(4)

Table of Contents

(b)(4)

(b)(4)

(b)(4)

1 Purpose

(b)(4)

(b)(4)

(b)(4)

2 Scope

(b)(4)

(b)(4)

3 Reference Documents

(b)(4)

(b)(4)

4 Definitions

(b)(4)

(b)(4)

5 Responsibilities

(b)(4)

(b)(4)

6 Software Architecture

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11 Treatment Sequencing

(b)(4)

(b)(4)

(b)(4)

(b)(4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40
9200 Corporate Blvd.
Rockville, Maryland 20850

April 28, 2008

ZELTIQ AESTHETICS
4698 WILLOW ROAD
PLEASANTON, CA 94588
ATTN: DONALD V. JOHNSON

510(k) Number: K080118
Product: ZELTIQ AESTHETICS CLN1 DERMAL COOLING DEVICE

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

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If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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K-46

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
04/25/2008	MD6031965-956733	K080118 /52

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☑ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☑ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Zeltiq Aesthetics, Inc.	Establishment Registration Number *(if known)*:
Division Name *(if applicable)*:	Phone Number *(including area code)*: ((b)(4) (b)(4)
Street Address: 4698 Willow Road	FAX Number *(including area code)*: ((b)(4) (b)(4)
City: Pleasanton	State / Province: CA; ZIP/Postal Code: 94588; Country: USA
Contact Name: Donald V. Johnson	
Contact Title: Vice President, Operations, Quality and Regulatory Affairs	Contact E-mail Address: (b)(4) (b)(4)

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name:	
Division Name *(if applicable)*:	Phone Number *(including area code)*: ( )
Street Address:	FAX Number *(including area code)*: ( )
City:	State / Province: ; ZIP/Postal Code: ; Country:
Contact Name:	
Contact Title:	Contact E-mail Address:

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Sterilization
  - [ ] Packaging
  - [ ] Other *(specify below)*

- [ ] Response to FDA correspondence:

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Repose to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [x] Other Reason *(specify)*:

Response to questions regarding K080118 in letter from FDA dated March 28, 2008.

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GEX	2	ILO	3	ISA	4	MSX
5	NUV	6	IRO	7		8	

Summary of, or statement concerning, safety and effectiveness information

- ☐ 510 (k) summary attached
- ☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K072152	1	CLN1 Dermal Cooling Device	1	Zeltiq Aesthetics, Inc.
2	K030876	2	Cynosure Triactive Therapeutic Massager	2	Cynosure, Inc.
3	K023231	3	Elfcare	3	Mediseb
4	K992749	4	Ultraview Waveform Pager System	4	Spacelabs Medical, Inc.
5	K070092	5	Velasmooth	5	Syneron Medical, Ltd.
6	K990445	6	Therapeutic Massager	6	LPG USA

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

	Trade or Proprietary or Model Name for This Device		Model Number
1	Zeltiq Aesthetics CLN1 Dermal Cooling Device	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K072152	2 K063715	3 K060407	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
ILO, GEX, ISA	890.5720, 878.4810, 890.5660	☐ Class I ☑ Class II ☐ Class III ☐ Unclassified

Classification Panel

Indications *(from labeling)*

The Zeltiq CLN1 Dermal Cooling Device is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq CLN1 Dermal Cooling Device can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)* K080118

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)* ( )	
Street Address		FAX Number *(including area code)* ( )	
City		State / Province	ZIP/Postal Code Country
Contact Name	Contact Title		Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)* ( )	
Street Address		FAX Number *(including area code)* ( )	
City		State / Province	ZIP/Postal Code Country
Contact Name	Contact Title		Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)* ( )	
Street Address		FAX Number *(including area code)* ( )	
City		State / Province	ZIP/Postal Code Country
Contact Name	Contact Title		Contact E-mail Address

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

Zeltiq
AESTHETICS

April 25, 2008

APR 28 2008
Received

Document Mail Center
510(k) Document Mail Center (HFZ-401)
Food and Drug Administration
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD 20850

RE: 510(k) submission – Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118)
Supplemental information request S-2

Dear Dr. Chen:

The following is in response to additional questions presented by FDA in a letter dated March 28, 2008.

1) Substantial Equivalence
In your response to deficiency #1 in FDA's letter dated February 27, 2008, you have provided a substantial equivalence matrix for the vacuum applicator (Table 1, K080118/S1) with additional predicates, LPG USA, K990445, and Syneron Vesasmooth, K070092. However, you did not update the substantial equivalence matrix for the Zeltiq CLN1 Dermal Cooling Device (Table 1, K080118) to include these two predicates. Please provide a revised substantial equivalence matrix for the Zeltiq CLN1 Dermal Cooling Device to include these two new predicates, if they are applicable.

The substantial equivalence matrix for the Zeltiq CLN1 Dermal Cooling Device (Table 1, K080118) has been revised to include the two additional predicates, LPG USA and Syneron Velasmooth. See the matrix in Attachment 1.

4698 Willow Road Pleasanton, CA 94588

2) *Directions for Use*

In your revised directions for use for the PL10691-D Zeltiq CLN1 Dermal Cooling Device (Attachment 2, K080118/S1), you did not include any treatment procedure recommended for different indications, specifically in the following categories: for minimizing pain and thermal injury during laser and dermatological treatments, for hot/cold therapy, and for massage therapy. Please revise your directions for use to include the general treatment procedure recommended for minimizing pain and thermal injury during laser and dermatological treatments, for hot/cold therapy, and for massage therapy.

The directions for use (DFU) for the Zeltiq CLN1 Dermal Cooling Device, PL10691-D, has been revised to include general treatment procedure recommendations. The procedures, such as for minimizing pain and thermal injury during laser and dermatological treatments, for hot/cold therapy, and for massage therapy, have been tabulated in Section 3.1 of the DFU. This table has been reproduced below for your convenience. The fully revised PL10691 is included as Attachment 2 of this submission.

Intended Use	**Profile**
Minimize pain and thermal injury during laser and dermatological treatments	(b)(4)
Skin cooling as a local anesthetic for procedures that induce minor local discomfort	
Localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms	(b)(4)
Temporary improvement in local circulation and temporary reduction in the appearance of cellulite	
Temporary relief of minor muscle aches, pain, and spasm, while utilizing the optional massage feature	

Table 1: Intended Uses and Treatment Profiles

3) Zeltiq Coupling Gel
In your response to deficiency #7, you indicate that the Zeltiq Coupling Gel is the same gel that was previously named the Juniper Coupling Gel. However, you did not clarify whether the Zeltiq Coupling Gel is (b)(4) (b)(4) *in the predicate, Juniper CLN1 Dermal Cooling Device (K072152). Please clarify.*

The following table was included in the response to deficiency #7:

New Name	Old Name	Submission
Zeltiq Coupling Gel	Juniper Medical Coupling Gel	K063715
Zeltiq Coupling Gel (b)(4)	Juniper Coupling Gel (b)(4)	(b)(4) (b)(4)
Zeltiq Coupling Gel	Juniper Coupling Gel	

(b)(4) (b)(4) (b)(4)

- (b)(4) (b)(4)
- All three gels are different but have the same function as a coupling gel.

(b)(4) (b)(4)
Inc. to Zeltiq Aesthetics, Inc.

In addition to the items above, the following two items and associated material were provided for informal review in response to interactive e-mail exchanges and teleconferences with the reviewer.

4) Indications for Use: It was noted that the word "temporary" did not appear in front of the indications: "improvement in local circulation" and "relief of minor muscle aches, pain, and spasm".

The directions for use (DFU) for the Zeltiq CLN1 Dermal Cooling Device, PL10691-D, has been revised to include the word "temporary" in front of these indications. Additionally, we have updated Section 6 (Indications for Use) and Section 7 (510K Summary) of our 510(k) submissions to include this language. These are included as Attachment 3.

5) Discussion of (b)(4) (b)(4) *Information to support the* (b)(4) (b)(4) *in Table 1 was requested.*

The (b)(4) (b)(4) is demonstrated with data collected during a study of human subjects in a clinical setting. (Note: This study is being performed to evaluate other device characteristics but includes data from a subset of subjects that is relevant to this discussion.) The attached report, Interim Clinical Summary Report: Protocol JM06-002 A Prospective Clinical Study of Non-invasive Cooling of Subcutaneous Fat in Patients Undergoing Abdominoplasty, documents interim results. This document has been included as Attachment 4.

Included among the profiles studied are six patients, (b)(4) (b)(4) through (b)(4) (b)(4) for whom (b)(4) (b)(4) (b)(4) (b)(4) For 3 of these six patients (b)(4) (b)(4) the period of (b)(4) (b)(4) (b)(4) (b)(4) Hence, the profile was equivalent to (b)(4) (b)(4) as stated in the directions for use.

A sample profile for (b)(4) (b)(4) is depicted in the graph below. Note that the (b)(4) (b)(4) (b)(4) (b)(4) The remaining patients (b)(4) (b)(4) (b)(4) (b)(4) in the directions for use.

In addition, to clarify, we have revised the directions for use to indicate that the (b)(4) (b)(4)

(b)(4)

(b)(4)

(b)(4) (b)(4)

We believe that, based on these data, the proposed (b)(4) (b)(4) is safe to use.

We trust that the additional information provides the clarification needed for completion of the review process for the subject submission. If there are any questions, or if additional information is required, however, please contact me at (b)(4) (b)(4) or by email at (b)(4) (b)(4)

Sincerely,

Donald V. Johnson
Vice-President, Operations, Quality, and Regulatory Affairs
Zeltiq Aesthetics, Inc.

Attachment 1: Substantial Equivalence Matrix

Element	Zeltiq CLN 1 Dermal Cooling Device (subject of this submission)	Juniper CLN1 Dermal Cooling Device K072152	ELFCare™ K023231	Cynosure Triactive Therapeutic Massage System K030876	LPG USA K990445	Syneron Velasmooth K070092
Indications for Use	• … used to minimize pain and thermal injury during laser and dermatological treatments…	• same				
	• Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort;	• same				
	For Hot/Cold Therapy…	For Hot/Cold Therapy…	For Hot/Cold Therapy…	For Hot/Cold Therapy…	For Hot/Cold Therapy…	For Hot/Cold Therapy…
	• localized thermal therapy (hot or cold) to minimize pain for post traumatic and / or post surgical pain;	• same	• same		NA	
	• for temporary relief of minor aches and pains and muscle spasms;	• same	• same	• same	NA	
	Massage Therapy…	Massage Therapy…		Massage Therapy…	Massage Therapy…	
	• temporary improvement in local circulation;	• same		• same	• same	
	• temporarily reduces the appearance of cellulite.	• same		• same	• same	• same
Principle of Operation						
Skin cooling / heating mechanism	Flat or cupped applicator, applied topically	Flat applicator, applied topically	Flat applicator, applied topically	Flat applicator, with slightly protruding rollers at the outer edges, applied topically	NA	Infrared power (up to 20w)

Element	Zeltiq CLN 1 Dermal Cooling Device (subject of this submission)	Juniper CLN1 Dermal Cooling Device K072152	ELFCare™ K023231	Cynosure Triactive Therapeutic Massage System K030876	LPG USA K990445	Syneron Velasmooth K070092
Applicator interface surface area	(b)(4) (b)	• same	6,500 mm^2	Variable, depending on attachment chosen		Maximum treated area is 40 x 40mm or 1,600 mm^2
Temperature control mechanism	Thermoelectric	• same	• same	Laser	NA	RF pwer
Treatment temperatures	(b)(4) (b)	• same	-(10)°C to 42°C	20 °C to 60°C (estimated)	NA	NA
Maximum recommended application time	(b)(4) (b)	• same	• same	Recommended treatment time: 30 minutes; maximum treatment duration not specified	30-45 minutes each session	Unknown
Vacuum function	Create skin fold	NA	NA	Create skin fold	Create skin fold	Create skin fold
Massage (e.g., mechanical manipulation)	Yes – electrically powered (vibration or pulsatile vacuum)	Yes – electrically powered (vibration)	NA	Yes – electrically powered (pulsatile vacuum)	Pulsatile vacuum and rollers	Pulsatile vacuum and/or massage
Massage with simultaneous heating	Yes, optional	Yes, optional	NA	Yes	No	Yes
Massage/cooling	Yes, possible contact cooling at skin. Precaution in DFU: "The effects of simultaneous use of massage and cold with the Zeltiq CLN1 Dermal Cooling Device have not been established, and such simultaneous use should be avoided."	Yes, possible contact cooling at skin. Precaution in DFU: "The effects of simultaneous use of massage and cold with the Zeltiq CLN1 Dermal Cooling Device have not been established, and such simultaneous use should be avoided."	NA	Yes, simultaneous superficial skin cooling	No	Yes, contact cooling on skin
Design Features						

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Element	Zeltiq CLN 1 Dermal Cooling Device (subject of this submission)	Juniper CLN1 Dermal Cooling Device K072152	ELFCare™ K023231	Cynosure Triactive Therapeutic Massage System K030876	LPG USA K990445	Syneron Velasmooth K070092
General Design	Unit attached to a hand-held patient interface; optional strap available for hands-free application	• same	Hands-free application with adjustable strap	Unit attached to a hand-held patient interface	NA	Unit attached to a hand-held patient interface
Temperature accuracy	(b)(4)	• same	±1°C	unknown	NA	Unknown
Temperature display	Computer screen and LCD	• same	• same	LCD	NA	Unknown
Power Source	AC	• same	AC/Optional Battery	• same	NA	• AC
Microprocessor controlled	Yes	• same	• same	• same	NA	Unknown
Safety Shut-off	Yes – auto shut off	• same	• same	Yes	NA	Unknown
Console with electrically powered vacuum pump	Yes	NA	NA	Yes	Yes	Yes
Pulsatile vacuum	Yes	Yes	NA	Yes	Yes	Yes
Suction power	(b)(4)	NA	NA	Unknown	37-375 mm Hg (50 -500 mBar Hg)	150 mm Hg (200 mbar)
Frequency	1-10 Hz	NA	NA	0.1 -5 Hz	0.41 – 19.23 Hz	Unknown
Cycle rate	50%	NA	NA	10-90%	10-90%	Unknown
Power Source	120 VAC/ 60 Hz	120 VAC/ 60 Hz	NA	120 VAC/ 60 Hz	120 VAC/ 60 Hz	120 VAC/60 Hz
Sterility	Non sterile	Non sterile	NA	Non sterile	Non sterile	Non sterile
Other Features						
Reusable	Yes	• same	• same	• same	• same	• same

Attachment 2: PL10691-E Zeltiq CLN1 Dermal Cooling Device

Zeltiq

Zeltiq CLN1 Dermal Cooling Device
Directions for Use

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Zeltiq Aesthetics, Inc.
4698 Willow Road
Pleasanton, CA 94588
(925) 474-2500
www.zeltiq.com

Authorized Representative
Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

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Pages 649 through 668 redacted for the following reasons:
- -
User Manual, not distributed publicly, b4

Attachment 3: Revised Section 6 (Indications for Use) and Section 7 (510K Summary)

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K080118

Device Name: Zeltiq CLN1 Dermal Cooling Device

Indications for Use:
The Zeltiq CLN1 Dermal Cooling Device is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq CLN1 Dermal Cooling Device can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.

The Zeltiq Coupling Gels facilitate thermal contact of the Zeltiq CLN1 Dermal Cooling Device with a patient's skin by mitigating minor variances in device-to-skin contact.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

SECTION 7. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

2. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	Zeltiq Aesthetics, Inc. 4698 Willow Road Pleasanton, CA 94588
TRADE NAME:	Zeltiq Cooling Device
COMMON NAME:	Skin Refrigerant
CLASSIFICATION NAME:	Laser instrument, surgical, powered
DEVICE CLASSIFICATION:	Class II, 21 CFR §878.4810
PRODUCT CODE	79 GEX – laser instrument, surgical, powered 89 IOL - pack, hot or cold, water circulating 89 ISA - massager, therapeutic, electric
PREDICATE DEVICE:	The Zeltiq CLN1 Dermal Cooling Device is substantially equivalent in intended use and mechanism of action to the Juniper CLN1 Dermal Cooling Device (K072152). The device is also substantially equivalent to the Cynosure Triactive Therapeutic massager (K030876).

SUBSTANTIALLY EQUIVALENT TO:

The Zeltiq CLN1 Dermal Cooling Device is substantially equivalent in intended use and mechanism of action to the Juniper CLN1 Dermal Cooling Device (K072152) and the Cynosure Triactive Therapeutic massager (K030876). The pager device used in the Zeltiq CLN1 Dermal Cooling Device is substantially equivalent to the Spacelabs Ultraview Waveform Pager System (K992749).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Zeltiq CLN1 Dermal Cooling Device is a thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The device also includes the option of electrically powered or pulsatile vacuum massage.

SECTION 7. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

INDICATION FOR USE:

The Zeltiq CLN1 Dermal Cooling Device is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq CLN1 Dermal Cooling Device can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.

The Zeltiq Coupling Gels facilitate thermal contact of the Zeltiq CLN1 Dermal Cooling Device with a patient's skin by mitigating minor variances in device-to-skin contact.

TECHNICAL CHARACTERISTICS:

The Zeltiq CLN1 Dermal Cooling Device is a thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The optional massage feature uses electrically powered vibration or pulsatile vacuum, depending on the applicator.

PERFORMANCE DATA:

Testing confirms that the Zeltiq CLN1 Dermal Cooling Device can be used in an equivalent manner to the predicate devices.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The indications for use for the Zeltiq CLN1 Dermal Cooling Device are the same as for the predicate devices cited in this application. A technological comparison and bench testing demonstrate that the Zeltiq CLN1 Dermal Cooling Device is functionally equivalent to the predicate devices.

Attachment 4: Interim Clinical Summary Report: Protocol JM06-002 A Prospective Clinical Study of Non-invasive Cooling of Subcutaneous Fat in Patients Undergoing Abdominoplasty

INTERIM CLINICAL SUMMARY REPORT
Protocol JM06-002
A Prospective Clinical Study of Non-invasive Cooling of Subcutaneous Fat in Patients Undergoing Abdominoplasty
February 2008

1. INTRODUCTION

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2. PURPOSE

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3. OBJECTIVES

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4. METHODS

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6. CONCLUSIONS

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