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).

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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

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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

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