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	Juniper Medical, Inc. 7139 Koll Center Parkway, Suite 300 Pleasanton, CA 94566
TRADE NAME:	Juniper Cooling Device
COMMON NAME:	Skin Refrigerant
CLASSIFICATION NAME:	Laser instrument, surgical, powered
DEVICE CLASSIFICATION:	Class II, 21 CFR §878.4810
PRODUCT CODE	GEX
PREDICATE DEVICE:	The Juniper Cooling Device is substantially equivalent to the Paradgim-Trex LLC DermaChiller 4 (K014253), to the Zimmer Elektromedizin GmbH Cryo 5 (K040727), to the Cutera Optional Pulse Light Hand Piece (K050047), and to the Opusmed F1 Diode Laser System (K030235).

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SUBSTANTIALLY EQUIVALENT TO:

The Juniper Cooling Device is substantially equivalent to the Paradgim-Trex LLC DermaChiller 4 (K014253), to the Zimmer Elektromedizin GmbH Cryo 5 (K040727), to the Cutera Optional Pulse Light Hand Piece (K050047), and to the Opusmed F1 Diode Laser System (K030235).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Juniper Cooling Device a thermoelectric cooling device that applies controlled cooling to a treatment site.

INDICATION FOR USE:

The Juniper 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.

TECHNICAL CHARACTERISTICS:

The Juniper Cooling Device is a thermoelectric cooling device.

PERFORMANCE DATA:

Testing confirms that the Juniper 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 Juniper Cooling Device are the same as predicate devices cited in this application. A technological comparison and bench testing demonstrate that the Juniper 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 3 1 2006

Juniper Medical, Inc.
% Ms. Rosemary Harry
Acting VP of Clinical and Regulatory
Affairs
7139 Koll Center Parkway, Suite 300
Pleasanton, California 94566

Re: K060407
Trade/Device Name: Juniper 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: May 12, 2006
Received: May 15, 2006

Dear Ms. Harry:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

K060407

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K060407

Device Name: Juniper Cooling Device

Indications for Use:

The Juniper 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.

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)

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

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