K 063715

5. 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
	FEB 05 2007
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	79 GEX – laser instrument, surgical, powered 89 IOL - pack, hot or cold, water circulating 89 ISA - massager, therapeutic, electric
PREDICATE DEVICE:	The Juniper Cooling Device XTRA is substantially equivalent in intended use and mechanism of action to the Juniper Cooling Device (K060407) and the MediSeb's ElfCare thermal therapy device for both hot and cold applications (K023231, cleared on April 4th, 2003). The device is also substantially equivalent to the Cynosure Triactive Therapeutic massager (K030876). Also included in this submission is the Juniper Medical Coupling Gel, which is intended to be supplied as an optional consumable supply. The gel is substantially equivalent in intended use and mechanism of action to the coupling fluid provided optionally with the Thermage ThermaCool System (K05170), and is substantially equivalent in composition to Pharmaceutical Innovation's Evron Gel (K961222).

SUBSTANTIALLY EQUIVALENT TO:

The Juniper Cooling Device XTRA is substantially equivalent in intended use and mechanism of action to the Juniper Cooling Device (K060407) and the MediSeb's ElfCare thermal therapy device for both hot and cold applications (K023231, cleared on April 4th, 2003). The device is also substantially equivalent to the Cynosure Triactive Therapeutic massager (K030876). Also included in this submission is the Juniper Medical Coupling Gel, which is intended to be supplied as an optional consumable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Juniper Medical, Inc.
% Mr. Don Johnson
Vice President, Regulatory,
Clinical & Quality Affairs
7139 Koll Center Parkway
Suite 300
Pleasanton, California 94566

FEB 5 2007

Re: K063715
Trade/Device Name: Juniper Cooling Device XTRA
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, ILO, ISA
Dated: December 13, 2006
Received: December 14, 2006

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.

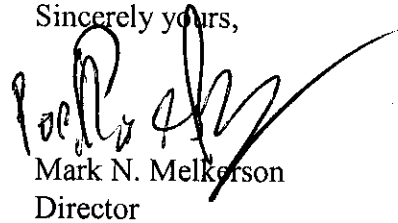
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K063715

Device Name: Juniper Cooling Device XTRA

Indications for Use:
The Juniper Cooling Device XTRA 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 Juniper Cooling Device XTRA 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 Juniper Medical Coupling Gel facilitates thermal contact of the Juniper Cooling Device XTRA 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)

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

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