K072152

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. 4698 Willow Road Pleasanton, CA 94588
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 CLN1 Dermal Cooling Device is substantially equivalent in intended use and mechanism of action to the Juniper Cooling Device (K060407), the Juniper Cooling Device XTRA (K063715), and the MediSeb's ElfCare thermal therapy device for both hot and cold applications (K023231). The device is also substantially equivalent to the Cynosure Triactive Therapeutic massager (K030876). Also included in this submission are the Juniper Medical Coupling Gels 400 and 600. The gels are substantially equivalent in intended use and mechanism of action to the coupling gel provided with the Juniper Cooling Device XTRA and the Thermage ThermaCool System (K051710).

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DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Juniper 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 massage.

SECTION 5. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

INDICATION FOR USE:

The Juniper 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 Juniper 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 Juniper Medical Coupling Gels 400 and 600 facilitate thermal contact of Juniper Dermal Cooling Devices with a patient's skin by mitigating minor variances in device-to-skin contact.

TECHNICAL CHARACTERISTICS:

The Juniper 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.

PERFORMANCE DATA:

Testing confirms that the Juniper CLN1 Dermal Cooling Device system can be used in an equivalent manner to the predicate devices. The Juniper Medical Coupling Gels 400 and 600 can be safely applied to the skin prior to use with Juniper Dermal Cooling Devices.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The indications for use for the Juniper CLN1 Dermal Cooling Device system are the same as for the predicate devices cited in this application. A technological comparison and bench testing demonstrate that the Juniper CLN1 Dermal Cooling Device system and the Juniper Medical Coupling Gels 400 and 600 are functionally equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Juniper Medical, Inc.
% Mr. Donald V. Johnson
4698 Willow Road
Pleasanton, CA 94588

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Re: K072152
Trade/Device Name: Juniper Cooling Device
Regulation Number: 21 CFR 890.5720
Regulation Name: Water circulating hot or cold pack
Regulatory Class: II
Product Code: ILO
Dated: August 1, 2007
Received: August 6, 2007

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 toll-free number (800) 638-2041 or (240) 276-3150 or the 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): _____

Device Name: Juniper CLN1 Dermal Cooling Device

Indications for Use:
The Juniper 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 Juniper 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 Juniper Medical Coupling Gels 400 and 600 facilitate thermal contact of Juniper Dermal Cooling Devices 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

510(k) Number K092152