APR 2 3 2004

K040727

Zimmer MedizinSysteme

Konzepte für Zukunft

510(k) SUMMARY

Date Prepared: 19/1/2004

Submitter:
Zimmer Elektromedizin GmbH
Junkersstrasse 9
D - 89231 Neu-Ulm
Germany
Contact Person: Mr. Stefan Leinweber
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E-mail: s.leinweber@zimmer.de

Device Trade Name: Cryo 5

Common Name: Skin Refrigerant

Classification: Class II (21CFR 878.4810)
Laser surgery instrument for use in general and plastic surgery and dermatology.

Performance Standards: None established (as a medical device) under section 514.

Description of Device: The Cryo 5 consists of a refrigeration unit that creates cold air. The cold air is blown onto the skin using an air hose.

Intended use of the Device: The Cryo 5 Cold Air Device is intended to minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections.

Substantial Equivalence Claim to the following legally marketed devices:

1. Cryo 5 (Nidek) K 013864
2. Paradigm Trex K 014253

Summary of Substantial Equivalence:

The Zimmer Cryo 5 is substantially equivalent to the compared devices on the basis of similarities in operating principles, intended use and functional performance.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2004

Zimmer Elektromedizin GmbH
c/o Mr. Stefan Preiss
TÜV America, Inc.
1775 Old Highway 8
New Brighton, Minnesota 55112

Re: K040727
Trade/Device Name: Cryo 5
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 16, 2004
Received: April 19, 2004

Dear Mr. Preiss:

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 (301) 594-4659. 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K040727

Indications for Use

510(k) Number (if known):	(none)
Device Name:	Cryo 5
Indications for Use:	The Cryo 5 Cold Air Device is intended to minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections.

Prescription Use ☒ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ☐ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K040727

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