

OCT 8 1999



TECHNOSANAT Innovative Medizintechnik Joerg Trempert, Gewerbepark Keplerstrasse 10 -12, 07549 Gera, Germany

K992536

510(k) SUMMARY

TECHNOSANAT KRYO TSK 2005

This 510(k) summary of safety and effectiveness for the TECHNOSANAT Innovative Medizintechnik TECHNOSANAT KRYO TSK 2005 is submitted in accordance with the requirements of 21 CFR Part 807 Subpart E § 807.92 and follows the DSMA Office of Health and Industry Programs Guidance: Premarket Notification 510(k) – Regulatory Requirements for Medical Devices (HHS Publication FDA 95-4158, August 1995) concerning the requirements for a 510(k) Summary and Statement.

Applicant: TECHNOSANAT
Innovative Medizintechnik

Address: Gewerbepark Keplerstrasse 10 -12
07549 Gera, Germany

Contact Person: Joerg Trempert
President

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Preparation date: July 10, 1999

Device name: Cooling device TECHNOSANAT KRYO TSK 2005

Common Name: TECHNOSANAT KRYO TSK 2005

Classification Name: Cooling device as accessories to a Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
Product code: GEX – Laser instrument, surgical, powered
Panel: SU

Legally marketed devices (SE): The Technosanat Kryo TSK 2005 is substantially equivalent to the Palomar E2000 System, Laserscope Coolspot, Optimed Dermacool and the Candela Dynamic cooling device. The operating principle of these devices is topical application of a low-temperature material to the surface of the skin in order to reduce its temperature.

See also Table of Comparison.

Device Description: TECHNOSANAT KRYO TSK 2005 is a skin-cooling device designed for support of laser treatment. The device consists of a control device and the treatment applicator which are connected via hose lines. Cold is generated in the applicator by means of Peltierelement, and directed to the patient via a metallic finger transfer medium. A piece of cooled metal comes in contact with skin and performs skin cooling. The treatment temperature is recorded by means of one temperature sensor in the applicator and is then displayed on the device's temperature controller.

Intended Use: TECHNOSANT KRYO TSK 2005 is intended for use in conjunction with a laser to provide surface cooling during cutaneous laser treatment and is a cooling device indicated for:

1. The reduction of pain associated with laser treatment,
2. Less discomfort,
3. Cooling of the skin just before the laser impulse treatment.

Comparison to: The intended use of the TECHNOSANT KRYO TSK 2005 is substantially equivalent to predicate devices in that they are intended to reduce pain and minimize thermal injury to skin structures during laser therapy.

Performance data: None. The specifications and intended uses of TECHNOSANT KRYO TSK 2005 are the same or very similar to those of claimed predicate devices. Because of this, performance data were not required.

CONCLUSION: The risks and benefits for the TECHNOSANT KRYO TSK 2005 are comparable to the predicate devices when used for similar clinical applications and therefore is the TECHNOSANT KRYO TSK 2005 substantially equivalent to legally marketed devices.



OCT 8 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Technosant Innovative Medizintechnik, GMBH
C/o Mr. William Kelley
Aesculap-Meditec North America
2525 McGaw Avenue
Irvine, California 92623

Re: K992536
Trade Name: TECHNOSANAT KRYO TSK 2005
Regulatory Class: II
Product Code: GEX
Dated: July 7, 1999
Received: July 29, 1999

Dear Mr. Kelley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

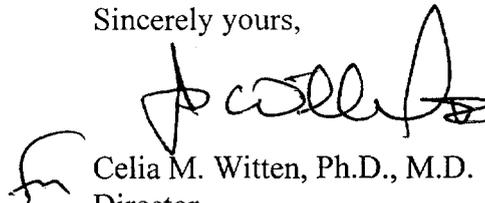
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. William Kelley

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', is written over the typed name.

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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K992536

Device Name: TECHNOSANAT KRYO TSK 2005

Indications For Use:

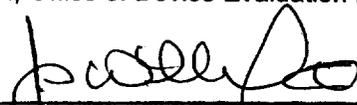
TECHNOSANAT KRYO TSK 2005 is intended for use in conjunction with a laser to provide surface cooling during cutaneous laser treatment and is a cooling device indicated for:

1. The reduction of pain associated with laser treatment,
2. Less discomfort,
3. Cooling of the skin just before laser impulse treatment.

Refer to the user manual for the laser to which the device is attached for cleared indications for use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K992536

Prescription Use

OR

Over-The-Counter Use _____