K031551

AUG 2 0 2003

Section E

5.0 510(k) Summary:

The following is a summary of the information contained in this traditional 510(k) application.

5.1 Submitter:

Vyteris Inc.
13-01 Pollitt Drive
Fair Lawn, NJ 07410
Phone: 201-703-2299
Fax : 201-703-2295

5.2 Contact:

George M. Baskinger
Manager, Quality Management and Regulatory Compliance

5.3 Device Name:

Name- Northstar Lidocaine Iontophoretic Controller (Northstar Controller-D)

Classification Name- Iontophoresis Device

Classification- Class II (special controls) pursuant to FR Doc.00-21251 filed 8-21-00 and 21CFR890.5525 paragraph a (revised April 1, 2002)

5.4 Predicate Device:

Iontophoresis Device
Phoresor® II, Model PM900
K974855 & K982668

Manufactured by:
IOMED, Inc.
3385 West 1820 South
Salt Lake City, UT 84104

000024

5.5 Description of Device:

The Northstar Lidocaine Iontophoretic Drug Delivery System (Northstar System) is composed of the Controller and the pre-medicated Patch. The Controller is fitted with a unique interconnect device, mating only with the Northstar Patch.

The Northstar System delivers drugs through a process known as iontophoresis. It is based on the principle that a soluble salt or drug can be transported across the skin barrier as a part of an electric current induced in the skin.

The quantity and distribution of delivered drug(s) is dependent on; ion charge, molecular weight, the intensity of the electric current and the time the current is present. In most iontophoretic systems the delivery is measured in terms of milliampere-minutes (mA-min).

It has been shown that the efficacious delivery of anesthetic levels of lidocaine hydrochloride can be made to local dermal areas through iontophoresis.

5.6 Intended Use of the Device:

Northstar System is indicated for the administration of lidocaine hydrochloride to provide local dermal anesthesia on normal intact skin. This system is an alternative to hypodermic injection or topical application of lidocaine hydrochloride.

Northstar System is indicated for use on patients 5 years of age and older.

5.7 Technical Characteristics:

The Northstar Controller-D uses a combination of discrete analog circuitry to control the delivery current and an embedded microprocessor to monitor the delivery.

The Northstar System utilizes a solid-state electronic controller and a pre-medicated drug delivery patch to form a simplified iontophoretic drug delivery system. As a result of this product design coordination, the Northstar System requires no special patch preparation or delivery parameter selection in the controller. An ON button actuation turns on an LCD (Liquid Crystal Display) indicating the number of deliveries

available, starts the delivery and two LED's (Light Emitting Diodes) on the controller indicate the delivery status to the user.

The Northstar System has been specifically designed for the delivery of a proprietary preparation containing 10.0% Lidocaine hydrochloride and 1.0% Epinepherine packaged in a pre-filled patch. The delivery is done over a 10 minute interval. The user simply applies the patch to the patient, connects the controller and patch then depresses the ON button to start the delivery.

5.8 Predicate Device Comparison:

The Northstar Lidocaine Iontophoretic Drug Delivery System and the IOMED Numby® 900 Iontophoretic Drug Delivery System have substantially the same function, that is to provide local dermal anesthesia. They both use the same drugs, lidocaine and epinepherine, to accomplish the result.

The Controllers for these systems (Northstar Lidocaine Iontophoretic Controller and the predicate device Phoresor® II, Model PM900) are both constant current generators. Both devices have similar safety features for over and under current delivery detection.

The differences in controller output characteristic are the result of differences in the drug concentrations used in the delivery. The predicate device uses a drug preparation of slightly lower concentrations requiring an increased charge to achieve similar levels of anesthesia.

5.9 Performance Summary

The Northstar Lidocaine Iontophoretic Drug Delivery System is a combination product consisting of an iontophoretic patch (drug component) and a controller (device component). The performance of the Northstar Lidocaine Iontophoretic Drug Delivery System were evaluated as a system by the end user during Phase III clinical studies to provide safety and efficacy data in support of the indication of local dermal anesthesia on intact skin which has been submitted as a part of the Northstar Lidocaine Iontophoretic Drug Delivery System New Drug Application (NDA) – N21-504 to CDER at the FDA.

These studies demonstrated the safety and efficacy of the Northstar Lidocaine Iontophoretic Drug Delivery System in achieving local dermal anesthesia on intact skin in both adults and pediatrics.

5.10 Conclusion

Overall, the controller of the Northstar system performed as intended to deliver the electrical current required to provide local dermal anesthesia to intact skin when used with the Northstar patch and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2003

Mr. George M. Baskinger
Manager, Quality Management
and Regulatory Compliance
Vyteris, Inc.
13-01 Pollitt Drive
Fair Lawn, New Jersey 07410

Re: K031551
Trade/Device Name: Northstar Lidocaine Iontophoretic Controller
(Northstar Controller D)
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis device
Regulatory Class: II
Product Code: KTB
Dated: May 16, 2003
Received: May 19, 2003

Dear Mr. Baskinger:

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), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the devices as described below. 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 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.

Our substantially equivalent decision does not apply to any specific drugs other than 10% Lidocaine and 1% Epinephrine packaged in a pre-filled patch submitted in NDA 21-504 for use with your device. Therefore, you may neither label nor promote your device for use with other specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland

As you are aware, iontophoresis devices that are intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses, if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, were classified into Class II. An iontophoresis device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes other than those specified for class II devices is classified into Class III (21 CFR 890.5525). We published our strategy for calling for premarket approval (PMA) applications in the enclosed Federal Register, dated May 6, 1994, and the enclosed memorandum, dated April 19, 1994, and the enclosed Federal Register, dated
August 22, 2000.

If you have any questions regarding this letter, you may contact:

Kevin Lee, M.D.
Food and Drug Administration
Center for Devices and Radiological Health
Division of General, Restorative and Neurological Devices
9200 Corporate Boulevard (HFZ-410)
Rockville, Maryland 20850
(301) 594-1296

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, please contact the Office of Compliance at (301) 594- 4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

for Mark N Milhous

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

Enclosures

Section D

4.0 Statement of Indications for Use:

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Northstar System is indicated for use on patients 5 years of age and older.

for Mark N Milleson

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

510(k) Number K031557