K063465

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IOMED®
First in Iontophoresis

FEB 2 8 2007

SUMARY OF SAFETY AND EFFECTIVENESS
Iontophoresis Drug Delivery Device
Date of Summary: **15 Nov 2006**

A. General Provisions

Submitter's Name:	IOMED, Inc.
Submitter's Address:	2441 South 3850 West, Suite A Salt Lake City, UT 84120-9941
Contact Person:	Curtis Jensen Director, Quality and Regulatory
Classification Name:	Iontophoresis Device 21 CFR 890.5525
Proprietary Name:	Champion Iontophoretic Drug Delivery System
Common Name:	Iontophoresis Drug Delivery Device

B. Name of Predicate Device(s)

- Iontophoresis Device: K974855 and K982668
  Iontophoresis Drug Delivery Device
  IOMED, Inc. Phoresor® II PM900
- Iontophoresis Device: K932621
  Iontophoresis Drug Delivery Device
  IOMED, Inc. TQ1 RH-801/GS
- Iontophoresis Device: K033192
  Iontophoresis Drug Delivery Electrode
  IOMED, Inc. RH-950

C. Device Description

An iontophoresis device is a device that is intended to use electrical current to introduce ions of water-soluble salts or drugs into the body for medical purposes. Iontophoresis technology is based on the principle that an electric potential will cause ions in solution to migrate according to their electrical charges. The quantity and distribution of a drug delivered into and across the skin by iontophoresis is dependent on the charge and molecular weight of the ion, the magnitude of the electrical current applied, patch composition, duration of current flow, and numerous other factors.

The IOMED, Inc. Champion integrated transdermal patch incorporates both a drug electrode and a return electrode. The patch is designed for a single-patient, one-application use and can only be used with IOMED's Champion dose controller. The Champion dose controller provides control of the current and therefore dosage delivered.

The Champion dose controller is a small, battery-powered, microprocessor-controlled iontophoretic device which delivers direct current (DC) to the integrated transdermal patch which is placed on intact skin.

D. Intended Use

Iontophoretic devices are indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injections. They are also indicated for iontophoretic dermal administration of IONTOCAINE® (Lidocaine HCl 2% and Epinephrine 1:100,000 Topical Solution).

E. Drug Delivery and Biocompatibility

Drug Delivery

Drug delivery rate measurements of both negatively and positively charged drugs were performed *in vitro* in freshly excised hairless mouse skin using the method described by Petelenz et. Al., *J Controlled Release* 20 (1992), 55-56. Commercial formulations of dexamethasone sodium phosphate (0.4% w/v dexamethasone phosphate equivalent) and lidocaine hydrochloride (4% w/v) were used as model drugs for cathodal (-) and anodal (+) iontophoresis, respectively. Drug quantifications in the skin and receptor solution was performed by radioassay using 3H-dexamethasone sodium phosphate and 14C-lidocaine hydrochloride tracers. The materials used in the Champion integrated transdermal patch are identical to those used in the RH-801/GS and the RH-950.

This testing shows that both negatively and positively charged drugs can be effectively delivered using the integrated transdermal patch to be used with the Champion Iontophoretic Drug Delivery System.

Safety and Biocompatibility

Primary dermal irritation studies were previously carried out in rabbits in accordance with FDA regulations for Good Laboratory Practices using Dexamethasone sodium phosphate and lidocaine hydrochloride as model compounds. Using standard Primary Dermal Irritation Index scores of 0.0 (non-irritant), 0.1 – 2.0 (mild irritant), 2.1 – 5.9 (moderate irritant), and 6.0 and greater (severe irritant), the RH-801/GS was rated as a mild irritant (0.5) during lidocaine administration, a non-irritant during a Dexamethasone administration from a Dexamethasone/lidocaine (1:2) mixture, and a non-irritant during Dexamethasone administration alone. The materials used in the Champion integrated transdermal patch are identical to those used in the RH-801/GS and the RH-950.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

IOMED, Inc.
% Mr. Curtis Jenson
Director, Quality and Regulatory
2441 South 3850 West, Suite A
Salt Lake City, Utah 84120-9941

FEB 2 8 2007

Re: K063465
Trade/Device Name: Champion Iontophoresis Drug Delivery Device
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis device
Regulatory Class: III
Product Code: EGJ
Dated: February 6, 2007
Received: February 7, 2007

Dear Mr. Jensen:

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 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 device 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 the drugs that you will label or promote for use with your device. Therefore, you may neither label nor promote your device for use with 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 20857

As you are aware, there are concerns relating to the fact that no drug is currently labeled for administration via an iontophoresis device. The Agency currently is evaluating this public health concern regarding the safety and effectiveness of this route of administration of drugs, and in the near future will inform manufacturers of certain additional steps the Agency believes are necessary to address this concern.

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 (240) 276-0120.

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 (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

2/26/07

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

Applicant: Iomed, Inc.

510(k) Number (if known): K063465

Device Name: Champion Iontophoretic Drug Delivery System

Indications For Use: Iontophoretic drug delivery devices are indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injections. They are also indicated for iontophoretic dermal administration of IONTOCAINE® (Lidocaine HCl 2% and Epinephrine 1:100,000 Topical Solution).

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)

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

510(k) Number K063465