K072946

Empi®

510(k) Summary

510(k) Owner's Name: Empi, Inc.
Address: 599 Cardigan Rd.
St. Paul, MN 55126

Phone number: 651-415-7344
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NOV 1 6 2007

Contact person: Sandra Walrod, Regulatory Affairs Associate
Date prepared: October 16, 2007

Trade name: Hybresis Iontophoresis Drug Delivery System
Common name: Iontophoresis Device

Classification name: Iontophoresis Device (21 CFR 890.5525)

Product Code: EGJ

Classification: III

Predicate device(s): Champion Iontophoresis Drug Delivery System
K063465 February 28, 2007

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 Empi Hybresis 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 Empi's Hybresis dose controller. The Hybresis dose controller provides control of the current and therefore dosage delivered.

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

Intended Use:

Iontophoresis 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.

Comparison to predicate:

The reason for this Special 510(k) submission, device modification, is for Empi to receive a clearance letter with the Hybresis Iontophoresis Drug Delivery System name and to inform FDA of the addition of two contraindications to the Hybresis IFU. The original 510(k) clearance letter is the Champion Iontophoresis Drug Delivery System, K063465, February 28, 2007.

Also, this submission is intended to demonstrate that the Hybresis has the same intended use as the predicate device and that there are no changes to the fundamental scientific technology and the basic considerations described in the guidance.

Non-clinical Testing:

Verification of the Hybresis includes electrical and mechanical tests to show that the device meets its product specifications over a range of operating and storage conditions. Validation testing for the Hybresis includes testing to show the device meets user needs according to marketing requirements.

Clinical Testing:

No prospective clinical studies are required to demonstrate safety and efficacy of the in support of applications for regulatory approval/clearance in the target markets. The Hybresis does not differ from the predicate devices in technological characteristics or intended use, where the device has a significant influence on clinical endpoints, and where prospective clinical studies would be necessary to determine safety and efficacy equivalence. The Product does not fit the profile of devices that might require clinical data per FDA guidance document 95-4158.

Conclusion:

The Empi Hybresis is substantially equivalent the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 6 2007

Empi, Inc.
% Ms. Sandra Walrod
Regulatory Affairs Associate
599 Cardigan Road
St. Paul, MN 55126

Re: K072946
Trade/Device Name: Hybresis Iontophoresis Drug Delivery System
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis device
Regulatory Class: Class III
Product Code: EGJ
Dated: October 30, 2007
Received: November 2, 2007

Dear Ms. Walrod:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

Indications for Use

510(k) Number (if known):

Device Name: Hybresis Iontophoresis Drug Delivery System

Indications for Use:

The Hybresis system is indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injections.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K072946