SEP 10 1999

Empi®

Cost Effective Health Care Solutions

K991991

Empi, Inc.
599 Cardigan Road
St. Paul, Minnesota
55126-4099 USA

651-415-9000
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SUMMARY OF SAFETY AND EFFECTIVENESS

Dupel® Iontophoresis Lead Wire Adapter
Date of Summary: June 11, 1999

A. General Provisions

Submitter's Name:	Empi, Inc.
Submitter's Address:	599 Cardigan Road St. Paul, Minnesota 55126-3965
Contact Person:	Kristy K. Mollner Regulatory Affairs Associate
Classification Name:	Iontophoresis Device 21 CFR 890.5525
Proprietary Name:	Dupel® Iontophoresis Lead Wire Adapter
Common Name:	Iontophoresis Lead Wire

B. Name of Predicate Devices

- Empi Dupel II Iontophoresis Electrodes K970491
- Empi Iontophoresis Buffered Electrodes K912015
- Dupel B.L.U.E. Electrodes K983484

- Iomed Phoresor Iontophoresis Device and Lead wires K780310, K872040, K934335, K974855, K982668

C. Device Description

The Empi Lead Wire Adapter will allow the use of currently marketed Dupel Electrodes with other commercially available iontophoresis devices.

D. Intended Use

The electrode is intended to be used in the clinic. Iontophoresis drug delivery systems are indicated for the local administration of ionic drug solutions into the body for medical purposes and can be used as an alternative to injections.

E. Non-Clinical and Clinical Test Summary

Non-Clinical Tests

Qualification was performed to establish suitability of performance between Dupel electrodes and lead wire adapters with other commercially available iontophoresis devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 1999

Ms. Kristy K. Mollner
Regulatory Affairs Associate
EMPI, Inc
599 Cardigan Road
St. Paul, Minnesota 55126-4099

Re: K991991
Trade Name: Dupel Iontophoresis Lead Wire Adapter
Regulatory Class: Class III
Product Code: EGJ
Dated: June 11, 1999
Received: June 14, 1999

Dear Ms. Mollner:

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 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 (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 requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

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

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.

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

Kevin Lee, M. D.
Division of General and Restorative Device
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850
Tel (301) 594-1296

This letter immediately will allow you to begin marketing your devices as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and permits your devices 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 . Additionally, for question on the promotion and advertising, please contact the Office of Compliance at (301) 594-4639. 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,

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

Enclosures

510(k) Number: (if known): Unknown at time of submission

Device Name: Dupel® Iontophoresis Lead Wire Adapter

Indications for Use:

Iontophoresis drug delivery systems are indicated for the local administration of ionic drug solutions into the body for medical purposes and can be used as an alternative to injections.

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 K991991

Prescription Use X OR Over-The Counter Use _____
(Per 21 CFR 801.109)