DEC 28 1998

K983484

Empi®

Cost Effective Health Care Solutions

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

651-415-9000
FAX 651-415-7305

SUMMARY OF SAFETY AND EFFECTIVENESS
Small Iontophoresis Electrode

Date of Summary: October 2, 1998

A. General Provisions

Submitter's Name:	Empi, Inc.
Submitter's Address:	599 Cardigan Road St. Paul, Minnesota 55126-3965
Contact Person:	Carolyn M. Steele Husten Regulatory Affairs Manager
Classification Name:	Iontophoresis Device 21 CFR 890.5525
Proprietary Name:	Dupel B.L.U.E Small Iontophoresis Electrode
Common Name:	Iontophoresis Electrode

B. Name of Predicate Devices

- Empi Dupel II Iontophoresis Electrodes — K970491
- Iomed Trans Q1 (RH-800) — K914621 and K925806
- Empi Iontophoresis Buffered Electrodes — K912015

C. Device Description

The Dupel® Buffered Iontophoresis Electrode System consists of an active drug delivery electrode and a passive return electrode. Both electrodes have buffering capability for up to a 160mA•min treatment session. These electrodes are designed for single patient, one application use. There are multiple sizes and shapes of drug delivery electrodes to accommodate placement at different body sites. The size of the return electrode is the same for all drug delivery electrode sizes.

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

The following parameters were verified: electrical resistance, pH buffering ability; fill rate, and material biocompatibility. The results of the functional testing were analyzed against product specifications and demonstrate that the product meets requirements, is acceptable for its intended use and is equivalent to the predicate electrodes.

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Non-Clinical Animal Tests

Using the standard Primary Dermal Irritation Index scores shown below the small electrode and the currently marketed small electrode was rated as a non-irritant or irritation barely perceptible after the 1st treatment when administered 2% lidocaine hydrochloride and epinephrine 1:100,000 (Lidocaine).

Clinical Tests

A performance evaluation of the new small electrode was conducted.. Based on the preliminary results the small electrode (current submission) is similar to the predicate electrode in terms of irritation, maximum comfortable current, conformance, adherence and leakage.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 28 1998

Ms. Carolyn M. Steele Husten
Regulatory Affairs Manager
EMPI, Inc.
599 Cardigan Road
St. Paul, Minnesota 55126-4099

Re: K983484
Dupel B.L.U.E™ Small Iontophoresis Electrode
Regulatory Class: III
Product Code: EGJ
Dated: October 2, 1998
Received: October 5, 1998

Dear Ms. Husten

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 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), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the devices as described below. **This substantially equivalent decision applies to indications for the local administration of ionic drug solutions into the body for medical purpose and can be used as an alternative to injections.**

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 practices, 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 any specific drugs 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,

Mark N Milhern

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

Enclosure

510(k) Number: (if known): Unknown at time of submission
Device Name: Small Iontophoresis Electrode
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)

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

Mark N. Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983484