SUMMARY OF 510(k) SAFETY AND EFFECTIVENESS INFORMATION

Empi®

Cost Effective Health Care Solutions

MAY 30 1997

Empi, Inc.
599 Cardigan Road
St. Paul, Minnesota
55126-3965 USA

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K970491

Applicant name:	Empi, Inc.
Applicant address:	599 Cardigan Road St. Paul, MN 55126-3965
Contact person:	Stacy Mattson, Regulatory Affairs Manager
Phone:	612-415-7354
FAX:	612-415-7314
Date Prepared:	February 6, 1997

Identification:

Classification Name:	Iontophoresis Device
Common/Usual Name:	Iontophoresis Electrode
Trade/Proprietary Name:	Dupel® II Buffered Iontophoresis Electrode System

Predicate Device:

Empi Buffered Iontophoresis Electrode (K912015)

Product Description:

The Dupel® II 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 160mAmin 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.

Intended Use:

The Dupel II Buffered Iontophoresis Electrode System is designed for use with the Dupel Iontophoresis Drug Delivery System. It is indicated for the local administration of ionic solutions into the body for medical purposes and can be used as an alternative to injections.

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Comparison of Technological Differences Between Original Electrodes and Modified Electrodes:

The modifications to the drug delivery electrode do not significantly impact the original product specifications for the Dupel® Buffered Iontophoresis Electrodes. The ability to buffer remains the same, the fill rate is the same, the active area is essentially the same, and the level of material biocompatibility is the same. The two parameters which have changed are electrical resistance and fill volume. The lowered resistance specification on the modified electrode may lengthen the device battery life. The fill volume has increased slightly but this parameter relates to convenience and does not impact the amount of drug that is delivered.

Assessment of Performance Data:

Non-Clinical Test Results

The following parameters were evaluated and/or tested: 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.

Conclusion from Testing

The data obtained from the design qualification tests demonstrate that this electrode is as safe, as effective and performs as well as the current Empi Electrode. In conclusion, the test results verified that the modified product is substantially equivalent to the currently marketed product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stacy Mattson, RAC, BSN
Regulatory Affairs Manager
Empi, Inc.
599 Cardigan Road
St. Paul, Minnesota 55126-3965

MAY 30 1997

Re: K970491
Dupel® II Buffered Iontophoresis
Electrode System
Regulatory Class: III
Product Code: EGJ
Dated: May 16, 1997
Received: May 19, 1997

Dear Ms. Mattson:

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 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 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 (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with

the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 drug 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.

I would also like to inform you that in the future, FDA intends to issue a proposed rule amending its regulations to require the filling of a PMA for all class III iontophoresis devices. The announcement will be published in the Federal Register. FDA intends that if a final rule is issued, based on the proposed rule, PMA's will be required to be submitted within 90 days of the effective date of the final rule.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice regarding labeling for your device in accordance with 21 CFR Part 801, promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their 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): K970491

Device Name: Dupel® II Buffered Iontophoresis Electrode System

Indications for Use:

The Dupel® II Buffered Iontophoresis Electrodes are designed for use with the Dupel Iontophoresis System (K903093) which is indicated for the local administration of ionic 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 K970491

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