K060814

JUN 14 2006

SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY: DYNATRONICS CORPORATION
7030 Park Centre Drive
Salt Lake City UT 84121
Phone: (800) 874-6251; (801) 568-7000; Fax: (801) 568-7711

1. DEVICE NAME (Trade/common, and classification):

Dynatron® Ion™ iontophoresis electrode

Classification:	Class III
Regulation Nos.:	890.5525
Product Codes:	EGJ

2. PREDICATE DEVICES:

North Coast Buffered Iontophoresis Electrode – cleared under K052019

3. PERFORMANCE STANDARDS: NA

4. DESCRIPTION:

The Dynatron® Ion™ iontophoresis electrode consists of an active drug delivery electrode and a return electrode. Electrodes are designed for single patient use.

5. INTENDED USE/INDICATIONS FOR USE:

The Dynatron® Ion™ iontophoresis electrode is designed for clinical use to introduce soluble salts and other drugs into the body as an alternative to hypodermic injection.

The Intended Use/Indications For Use stated herein are consistent with the cleared indications for the predicate device.

6. SUBSTANTIAL EQUIVALENCE (SE) RATIONALE:

The Dynatron® Ion™ iontophoresis electrode shares the same or similar basic characteristics, features and intended use as the predicate device and, therefore, is substantially equivalent to the North Coast Buffered Iontophoresis Electrode (applicable 'K' number listed above).

(page replaced see next page)

7. SAFETY AND EFFECTIVENESS: There are no substantive differences between the product defined in this 510(k) submission and the predicate device. They are similar to the technologies that are currently used in other similar medical devices. The product is safe and effective when used as indicated in specific applications under a clinician's supervision/therapy program.

Signed: _____ Dated: March 20, 2006

Kelvyn Cullimore, Jr., President and CEO
DYNATRONICS CORPORATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2006

Dynatronics Corporation
% Mr. Kelvyn Cullimore, Jr.,
President and CEO
7030 Park Centre Drive
Salt Lake City, Utah 84121

Re: K060814
Trade/Device Name: Dynatron® Ion™ iontophoresis electrode
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis devices
Regulatory Class: III
Product Code: EGJ
Dated: May 24, 2006
Received: May 26, 2006

Dear Mr. Cullimore:

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

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,

for

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

Indications for Use

510(k) Number (if known): K060814

Device Name: Dynatron® Ion™ iontophoresis electrode

Indications for Use:

The Dynatron® Ion™ iontophoresis electrode is indicated to introduce soluble salts and other drugs into the body as an alternative to hypodermic injection

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bruchup for MXM

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

510(k) Number K060814