K061522

Section E
510(k) Summary

AUG 0 1 2006

A. General Provisions

Submitter's Name: ActivaTek Inc
Submitter's Address: C/O PETERS SCOFIELD PRICE
340 Broadway Centre
111 E. Broadway
Salt Lake City, UT 84111
Contact Person: David Scofield
dws@psplawyers.com
(801) 322-2002 (ph); (801) 322-2003 (fax)

Classification Name: Iontophoresis, other uses
21 CFR 890.5525
Proprietary Name: ActivaTek *Trivarion* Buffered Iontophoresis Electrode System
Common Name: Iontophoresis Electrode

B. Date of preparation of this Summary: 5-31-2006

C. Name of Predicate Devices to which equivalence is claimed:

- Naimco *Iontoplus* Buffered Iontophoresis Electrode (k040495)
- Iomed *TransQ E* iontophoresis Electrode (k932630)

The ActivaTek *Trivarion* Iontophoresis Electrode is substantially equivalent to the identified iontophoresis electrodes in intended use, materials of construction, and mode of operation.

D. Device Description

The *Trivarion* Buffered Iontophoresis Electrode System consists of a disposable, single-use iontophoresis electrode and return electrode. A packaged 70% isopropyl alcohol patch (Becton Dickinson, Franklin Lakes, NJ 07417) is also included.

The *Trivarion* Iontophoresis Electrode System does not include the iontophoresis electrical generator or the electrical lead wires. Commercially available, FDA approved microprocessor controlled constant current generators such as the Iomed *phoresor* or EMPI *Dupel* may be connected to the *Trivarion* electrodes.

E. Statement of Intended Use Compared to Predicate Device(s)

The ActivaTek *Trivarion* Iontophoresis Electrode System has the same intended use as the above identified predicate devices and other iontophoresis devices, i.e., it is intended to be used for the local administration of ionic solutions into the body for medical purposes and as an alternative to injections.

F. Discussion of Technological Characteristics:

The *Trivarion* Iontophoresis Electrode is buffered by the use of silver-silver chloride for administered doses in the range of 40-80 mAmp*min for both polarities, negative and positive.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 1 2006

Activa Tek, Inc.
% Peters Scofield Price
Mr. David Scofield
340 Broadway Centre
111 East Broadway
Salt Lake City, Utah 84111

Re: K061522
Trade/Device Name: Trivarion Buffered Iontophoresis Electrode System
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis device
Regulatory Class: III
Product Code: EGJ
Dated: July 19, 2006
Received: July 20, 2006

Dear Mr. Scofield:

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

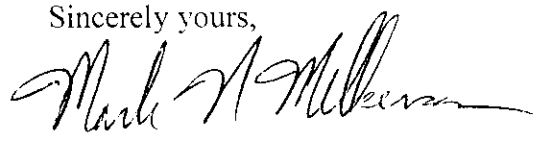
As you are aware, there are concerns relating to the fact that no drug is currently labeled for administration via an iontophoresis device. The Agency currently is evaluating this public health concern regarding the safety and effectiveness of this route of administration of drugs, and in the near future 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,



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): k061522

Device Name: Trivarion Buffered Iontophoresis Electrode System

Indications For Use: The Trivarion Buffered Iontophoresis Electrode System is intended to be used for the administration of soluble salts into the body for medical purposes and as an alternative to hypodermic injection.

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

510(k) Number K061522

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 In Vitro Diagnostic Devices (OIVD)