MAR - 3 2000

K993081

SUMMARY OF SAFETY AND EFFECTIVENESS

IO-DRIVE Iontophoresis electrode system
Date of Summary: Dec 14, 1999

A. General Provisions

Submitter's Name:	Selective Med Components, Inc.
Submitter's Address:	6 South Mechanic St.
	Mt. Vernon, Ohio 43050
Contact Person:	Rick Fisher
Classification Name:	Iontophoresis Device
Proprietary Name:	IO-Drive system
Common Name:	Iontophoresis electrodes
FDA 510 (k)	99-3081

B. Name of Predicate Devices

- Iomed TransQ K91-4621
- Empi Dupel K91-2014

C. Device Description

The IO-Drive Iontophoresis electrode system consists of an active drug delivery electrode and a return electrode. These electrodes are designed for single patient use. There are multiple sizes of drug delivery electrodes to accommodate placement at different body sites. The size of the return electrode is the same size for all drug delivery electrodes.

D. Inteneded 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. Test and Evaluation

A performance evaluation was performed and based on the evaluation the IO-Drive electrode is similar to the predicate electrodes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 2000

Mr. Richard John Fisher III
Chief Executive Officer
Selective Med Components, Inc.
6 South Mechanic Street
Mount Vernon, Ohio 43050

Re: K993081
Trade Name: IO-Drive System
Regulatory Class: Class III
Product Code: EGJ
Dated: December 14, 1999
Received: December 17, 1999

Dear Mr. Fisher:

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:

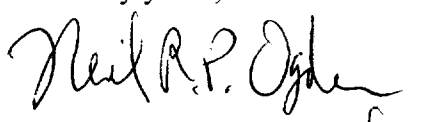
Kevin Lee, M. D.
Division of General and Restorative Device
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850
Tel (301) 594-1296

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,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510 (k) NUMBER (IF KNOWN) : K993081

DEVICE NAME: IO-DRIVE

INDICATIONS FOR USE:

Io-Drive electrode is indicated to introduce ions of soluble salts and other drugs into body.

NRO for JZD

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993081

Prescription Use YES
(Per 21 CFR 801.109)