JUN 1 6 2009

K083016

510(k) Summary
807.92(c)

SPONSOR **807.92(a)(1)**

Company Name:	Microlab Americas Inc.
Company Address	405 Rowntree Dairy Road, Unit 1 Woodbridge, Canada L4L 8H1
Telephone:	905-264-1935
Fax:	905-264-5571
Contact Person:	David Vanslingerland

Summary Preparation Date: September 16, 2008

DEVICE NAME **807.92(a)(2)**

Trade Name: ActhyDerm
Common Name: Iontophoresis Device
Classification Name: Device, Iontophoresis, Other Uses
Regulation Number: 21 CFR 890.5525
Product Code: EGJ
Device Class: III

PREDICATE DEVICE **807.92(a)(3)**

Company	Product	510(k) #
AA Advanced Technology Inc	Mesoderm	K061849

DEVICE DESCRIPTION **807.92(a)(4)**

ActhyDerm is a device that is a microprocessor controlled iontophoresis drug delivery system. The microprocessor has four pre-set programs for penetration of the 1) epidermis, 2) dermis, 3) adipose, 4) muscle. It has a dispersive electrode and roller electrodes. An FDA approved conductive grounding pad is also required prior to its use.

Introducing ions can be accomplished with ActhyDerm's Dispensing Electrode and roller using methods described in the operator's manual: roller conducts current to the skin via the product to be delivered. The product has a positive charge, the current coming into the roller has a positive charge and when they meet the product the ions are diffused into the skin.

DEVICE INTENDED USE **807.92(a)(5)**

ActhyDerm is indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injections.

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

Parameters	MesoDerm	ActhyDerm
510(k) Number	K061849	
Indications for Use:	MesoDerm is indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injections.	ActhyDerm is indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injections.
Power Supply	AC 110V~60Hz – 0.25A max	AC 110V~60Hz – 0.25A max
Average Pulse Current	< 5 mA	< 5 mA
Load Impendance	< 2 KOhm	< 2 KOhm
Pulse Frequency	200-2000Hz	200-2000Hz
Burst Time	2s	2s
Burst Frequency	0.25 – 50Hz	0.25 – 50Hz
Dispenser Head	Reusable	Reusable
Generator	Electrical pulses are produced by an electronic pulse generator that is able to generate bursts of pulses that are applied to the skin through electrodes applied	Electrical pulses are produced by an electronic pulse generator that is able to generate bursts of pulses that are applied to the skin through electrodes applied

Substantial Equivalence Discussion of Similarities and Differences:
ActhyDerm is identical to the predicate device in:

- Intended Use
- Materials
- Design
- Technological Characteristics

The ActhyDerm introduces no new questions concerning the safety or effectiveness and is thus substantially equivalent to the predicate device.

NONCLINICAL AND CLINICAL TEST 807.92(b)

SAFETY and EFFECTIVENESS
The electrical performance of the ActhyDerm meets the requirements of the following standards:
EN 60601-1 (1998, EN 62-24 (1997), 60601-1-2 (1998), EN55011 (1999), EN 61000-4-2 (1998), EN 61000-4-3 (1997), EN 61000-4 (1998), En61000-4-5

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Microlab Americas Incorporated
% E J Smith
Regulatory Consultant
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

JUN 16 2009

Re: K083016
Trade/Device Name: ActhyDerm
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis Device
Regulatory Class: III
Product Code: EGJ
Dated: May 7, 2009
Received: May 21, 2009

Dear E J Smith:

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 (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) that do not require approval of a premarket approval application (PMA). 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); medical device reporting

(reporting of medical device-related adverse events) (21 CFR 803); 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" (21CFR 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 (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ActhyDerm

Indications for Use:

ActhyDerm is indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injections.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083016

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