K061849

APR 30 2007

# AA Advanced Technologies Inc.
# 6422 W. Belmont Ave.
# Chicago, Illinois 60634 USA

DRAFT

## 510(k) Summary

**Company:** AA Advanced Technology Inc.
MesoDerm

**Contact Person:**

**Address:** 6422 W. Belmont Ave.
Chicago, Illinois 60634

**Phone:** 1-800-706-1186
**Fax:** 1-773-481-2516

**Product Code:** EGJ

**Classification Name:** Device, Iontophoresis, Specific Uses

**Codes of Federal Regulations:** 21 CFR 890.5525

**Predicate Device:**
K032968 & K042590 Transderm® System, Transderm Ionto System

## Device Description:

MesoDerm is a device that is a microprocessor controlled iontophoresis drug delivery system. It has a dispersive electrode, which is attached to the microprocessor. An FDA approved conductive grounding pad is also required prior to its use.

Introducing ions can be accomplished with MesoDerm's Dispensing Electrode and roller using methods described in the operator's manual. This is accomplished as the 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.

## Indication 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.

*MesoDerm*

| | |
|---|---|
| Operating Voltage: | 110V~ 60HZ |
| Assimilation: | 25W |
| Standards Met: | EN 60601-1 & 60601-1-2, EN 55011, EN 61000-4-2, EN 62-24, EN 61000-4-3, EN 61000-4, and EN 61000-4-5, IEC 950 (Reference Section 3) |
| Fuses: | 2 of 250mA Type T (retarded) |
| Operating Temperature: | 10-50° C Relative Humidity 10-100% |
| Weight: | 8Kg |
| Material Chassis: | Aluminum |
| Electronics: | Microprocessor Controlled |

Exit Channels — Galvanically insulated, protected by extra voltage and limited in electrical current

## 12.1 Substantial Equivalent Chart

Table 12.1 Substantial Equivalence Chart

| Parameters | MesoDerm | Transderm® System |
|---|---|---|
| 510(k) Number | | K032968 & K042590 |
| | | |
| 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. | The TRANSDERM IONTO System is a powered drug delivery system that is indicated for the local administration of ionic drug solutions into the body for medical purposes and can be used as an alternative to injections. |
| Power Supply | AC 110V~60Hz – 0.25A max | 9 V DC, 1A max |
| Average Pulse Current | < 5 mA | ±mA, 2 mA, 3 mA, 4 mA, 5 mA, user selectable, ±20% |
| Load Impendance | < 2 KOhm | 0-15 KOhm |
| Pulse Frequency | 200-2000 Hz | 2200 Hz |
| Burst Time | 2 sec | 10 msec. |
| Burst Frequency | 0.25 – 50 Hz | 50 Hz |
| Dispenser Head | Reusable | Disposable |
| 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. |

## Contraindications

MesoDerm is contraindicated in patients sensitive to the drug and in electrically sensitive patients (e.g., pacemaker carriers).

## Warnings and Precautions

MesoDerm is not to be used:

- on patients who have an allergy to any medication or solution to be administered
- subjects with metal and /or electric prosthesis
- pregnant women
- subjects with cardiac rhythm disorders
- subjects with pacemakers
- subjects with leg thrombophlebitis and phlebitis in acute phase
- subjects with large varices
- epileptic subjects
- subjects unable to comprehend and /or communicate
- it is contraindicated for use over damaged or denuded skin or orbital areas

## Caution:

Caution (U.S.A.) law restricts this device to sale by or on the order of a physician.

Iontophoresis can cause skin irritation or burns and the patient has to be informed before iontophoresis application.

**Standards Met:**

MesoDerm conforms to the following standards: EN 60601-1, EN 60601-1-2 (1998), EN 55011 (1999) ,EN 61000-4-2 (1998), EN 62-24, EN 61000-4-3 (1997), EN 61000-4 (1994), EN 61000-4-5 (1997), IEC 950.

**Product Specifications:**

*Roll on Ball*

| | |
|---|---|
| Material Choice: | **Polypropylene** |
| Nominal ball diameter: | 1.4" (35.56mm) |
| Other Specifications: | Standard diameter tolerance: ± 0.002" (±0.05mm)<br>Sphericity: 0.002" (0.05mm) |

*Conductive Grounding Plate*

| | |
|---|---|
| Material Choice: | Any FDA cleared grounding pad |

**Conclusion:** This device is substantially equivalent to the devices approved as K032968 & K042590.

**Smith**
- FDA CONSULTANTS -
Specializing in Regulatory Affairs

DRAFT

April 24, 2007

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: K061849

Dear Dora Vega:

AA Advanced Technology, Inc. has modified their device to remove the stylus referenced in 510(k) K061849. All references and performance information related to the stylus, including information used in labeling will be removed. Any references to default time for each treatment concerning Adipose Tissue, Muscle, Dermis and Epidermis will be removed.

The attached revised 510(k) summary accurately reflects the device under review less the stylus.

If you have any questions concerning this change please contact me at 410-451-0639.

Sincerely,

E.J. Smith

Cc: AA Advanced Technology

1676 Village Green • Suite A • Crofton, Maryland 21114
**PHONE:** (888) 729-9674 • **FAX:** (410) 793-0448
**WEB SITE:** www.fdaconsultants.com • **E-MAIL:** ESmith9746@aol.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AA Advance Technology, Inc.
% Smith Associates
Mr. E. J. Smith, Consultant
1676 Village Green
Crofton, Maryland 21114

APR 30 2007

Re: K061849
Trade/Device Name: Mesoderm - Iontophoresis Device
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis Devices
Regulatory Class: III
Product Code: EGJ
Dated: April 3, 2007
Received: April 4, 2007

Dear Mr. 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 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 20850

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): K061849

Device Name: MesoDerm

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.

Prescription Use ___X____ (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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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



**510(k) Number** K061849