510(k) Summary

Submitter's Identifications
Manufacturer and Sponsor
Avazzia, Inc.
13154 Coit Rd., Ste 200
Dallas, TX 75240 USA
Establishment Registration # 3004839404
Official Contact Person: Catherine Tone
Date of Summary Preparation: April 17, 2007

APR 30 2007

Trade Names of Devices
Body-Stim™, Biomodulator™, BEST-RSI™, BEST-Pro1™

Common Name
TENS device

Classification
TENS 882.5890 Class II

Information of the 510(k) Cleared Devices (Predicate Devices)
InterX5000, K042912, 17/May/2005

Description and Intended Use
The four Avazzia Biofeedback Electro-Stimulation Technology (BEST) devices are biofeedback, micro-current transcutaneous electro-stimulation devices for symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain. They are easy-to-use, handheld, AA battery-operated portable devices for use in the home or clinic.

The technological characteristics of these devices, including waveforms, outputs, and biofeedback are the same as the InterX5000.

The software verification has been conducted according to the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – Guidance for Industry and FDA Staff – May 11, 2005.

Avazzia has received a CB Test Certificate certifying that these four devices, all accessories and lead wires were tested and found to be in conformity with IEC 60601-1:1988 + A1:1991 + A2: 1995 and EMC:IEC 60601-1-2 (ed. 2) international safety standards for TENS devices. See certificate in TAB 8.

Additionally, Avazzia has received a CE Mark in the TENS category for the four devices, all accessories and lead wires in this submission certifying that we meet the EC-Directive 93/42/EEC (TAB 8).

Conclusions

The devices have intended uses and technological characteristics that are substantially equivalent to the predicate device InterX5000 (K042912). Moreover, verification and validation tests contained in this submission demonstrate that the submitted models are equivalent to the safety and effectiveness as that of the cleared devices.

Avazzia, Inc., 13154 Coit Rd., Ste 200, Dallas, TX 75240 USA tel. 214-575-2820 fax 214-575-2824

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Avazzia Inc
% Ms. Catherine Tone
13154 Coit Rd.
Suite 200
Dallas, Texas 75240

APR 3 0 2007

Re: K062641
Trade/Device Name: Body-Stim, Biomodulator, Best-RSI, Best Pro, Model Best-AV1
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: April 24, 2007
Received: April 20, 2007

Dear Ms. Tone:

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 such 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.

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 (21 CFR Part 801), 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use – Biomodulator™ and each of its modes

510(k) Number K062641
Device name: **Biomodulator**
Modes:

Assess
Ten-8
Infinity
Automatic

Indications for use:

For symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K062641

Indications for Use – Body Stim™ and each of its modes

510(k) Number K062641
Device name: **Body-Stim**
Modes:

Relax
RSI
VASO
Acute Trauma

Indications for use:

For symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use – BEST-RSI™ and each of its modes

510(k) Number K062641
Device name: **BEST-RSI**
Modes:

Relax
Deep Stimulation
RSI
Acute

Indications for use:

For symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use – BEST-Pro 1™ and each of its modes

510(k) Number K062641
Device name: **BEST-Pro 1**
Modes:

Assess
Stimulation
Deep Stimulation
Acute

Indications for Use:

For symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)