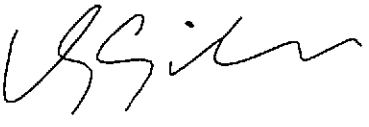
K081835

1 510(k) Summary

MAR 19 2009

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number:	k081835
The 510(k) submitter and owner's name is:	Bioinduction Limited
Address and registered office:	178-180 Hotwell Road, BRISTOL, BS8 4RP, United Kingdom
Telephone number:	+44 117 377 5275
Fax number:	+44 117 377 5405
Contact person:	Ivor S Gillbe, Chief Executive Officer
Date the summary was prepared:	21 December, 2008
Proprietary Name:	Acticare
Common Name:	TENS (Transcutaneous Electronic Nerve Stimulator) device NMES (Neuromuscular Electrostimulation) device
Classification Name:	GZJ: Stimulator, Nerve, Transcutaneous IPF: Stimulator, Muscle, Powered
Predicate Devices:	Acticare is similar to the following predicate devices: As a TENS device under classification GZJ: 1. Enraf Nonius Endomed 182 System (k003744), 2. Skylark PGS-123 High Voltage Galvanic Stimulator (k946299) 3. Rehabilicare (now Compex Technologies Inc.) ProMax TENS (k022405) 4. Body Clock Health Care Ltd V-TENS Plus (k022731) As a NMES device under classification IPF 5. BioStim NMS+ Electrical Neuromuscular Stimulator (k010749)
Device Description:	Acticare HFT/HFI is a hand-held stimulator designed to pass electrical signals via surface electrodes through the skin to the underlying nerves or muscles. It may be used as a TENS device to aid the blocking of pain signals traveling to the brain or as a NMES device for muscle stimulation.

Intended Use:	Transcutaneous Electronic Nerve Stimulation (TENS) is used for the symptomatic relief and management of pain and/or as an adjunctive treatment in the management of post surgical and post-traumatic acute pain. Neuromuscular Electrostimulation (NMES) is used for the relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis and to maintain or increase the range of motion. The device can be used in clinical, domestic and other environments.
Technology Comparison to Predicate Device:	Acticare is very similar to the predicate devices and has technology characteristics that are substantially equivalent to the predicate devices. Acticare and the five predicate devices all transmit electrical pulses through the skin. The range of amplitudes, pulse widths, frequencies and polarities delivered by Acticare is within the ranges delivered by the predicate devices. Acticare and the five predicate devices can all be used in clinical, domestic and other environments.
Non-clinical Testing:	The device was tested in accordance with the tests specified in IEC 60601-2-10:2001 supported by the following testing below:
IEC 60601-1:1988	IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
IEC 60601-1-1:2000	Safety requirements for medical electrical systems
IEC 60601-1-2:2005	EMC compatibility (and additional FCC requirements)
IEC 60601-1-4:2000	Software for use in Medical Devices.
Conclusion:	Acticare and the four predicate devices have the same intended uses and similar technical characteristics, performances and applications. The information supplied in the full 510(k) application illustrates that the device does not pose any new questions of safety or effectiveness. Acticare is substantially equivalent to the predicate devices.
Declaration:	This summary has been compiled in accordance with FDA guidelines and includes only information that is also covered in the body of the 510(k) and does not contain any puffery or unsubstantiated labeling claims.
Signed	 Ivor S Gillbe being a duly authorized officer of the company on 22nd December, 2008 on behalf of Bioinduction Limited, Bristol, UK.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 9 2009

Bioinduction Ltd.
% Ms. Krista Oakes
2300 McDermott Road, Suite 200-207
Plano, Texas 75025

Re: K081835
Trade Name: Bioinduction Acticare HFI and HFT
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ, IPF
Dated: February 27, 2009
Received: February 29, 2009

Dear Ms. Oakes:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

Enclosure

2 Statement of Indications for Use

510(k) Number (if known):	k081835
Device Name:	Bioinduction Acticare HFT/HFI
Indications For Use:	As a Transcutaneous Electronic Nerve Stimulation (TENS) device for: the symptomatic relief of chronic intractable pain, and as an adjunctive treatment in the management of post-surgical or post-traumatic pain. As a Neuromuscular Electrostimulation (NMES) device for: the relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis and to maintain or increase the range of motion.

Prescription Use: **YES** (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: **NO** (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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