SEP 2 0 2005

K051357

DIGITIMER Ltd - DS7A/DS7AH, 510(k) application

E - 510(k) Summary

Submitted by

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Company:	Digitimer Ltd
Address:	37 Hydeway Welwyn Garden City Herts AL7 3BE UK
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Authorised corespondent

Name:	Harry J Benedict Managing Partner
Company:	MEPs-LLC
Address:	One East Broward Blvd Suite 700 Fort Lauderdale FL 33301
Telephone:	(954) 713-8017
FAX:	(954) 523-1911

Contact person:	Harry J Benedict
Preparation date:	December 07, 2004
Device names:	Digitimer DS7A and DS7AH Constant Current High Voltage Stimulators
Common name:	Evoked Potential Stimulator
Classification name:	Evoked response electrical stimulator, per 21 CFR § 882.1870
Device class:	2
Product code:	GWF

Predicate device

510(k) Number:	K020400
Device Name:	Digitimer D185 Multipulse Cortical Stimulator
Common name:	Evoked Potential Stimulator
Classification Name:	Evoked response electrical stimulator, per 21 CFR § 882.1870
Device class:	2
Product Code:	GWF
Date Received:	02/06/2002
Decision Date:	08/23/2002

Device Description

The **Digitimer DS7A** Stimulator provides constant current high voltage pulses of brief duration for percutaneous stimulation during investigation of the electrical activity of nerve and muscle tissue. The output current is continuously variable over the range 0 to 100 milliamps, from a source voltage continuously variable from less than 100 volts to 400 volts, to meet the requirements of human pathological cases. Short pulse durations have been made available to minimise any discomfort to the subject. The pulse width range can be varied from 50 microseconds to 2 milliseconds in six steps. A specially designed isolated output stage maintains a square (current) pulse shape while minimising stimulus artefacts.

The **Digitimer DS7AH** Stimulator is a variant of the DS7A providing a higher maximum current at reduced pulse width. This option is offered to overcome the difficulty of stimulating deep peripheral nerves with large area electrode pads. The DS7AH option will provide a maximum stimulus current of 1 amp at up to 400 volts compliance at pulse widths up to 200 µs.

Indications for use

The DS7A and DS7AH are stimulators intended for use during neurological monitoring and assessment in a clinical environment.

They are intended for use by trained personnel either competent to apply appropriate stimuli or under the supervision and instruction of one who is.

Substantial Equivalence Comparison

Parameter	Predicate Device D185	DS7A	DS7AH
Intended application	Transcranial stimulation	Percutaneous stimulation	Percutaneous stimulation
Mode of operation	Constant voltage	Constant current	Constant current
Stimulus Output	Selected by continuously variable, multi-turn control, 0 to 1000 V (into 1k load)	Selected by continuously variable, multi-turn control and x1/x10 switch. Dial reading 0.00 to 9.99 giving 0 to 9.99 mA for x1 setting, and 0 to 99.9 mA for x10 setting	Selected by continuously variable, multi-turn control and x1/x10 switch. Dial reading 00.0 to 99.9 giving 0 to 99.9 mA for x1 setting, and 0 to 999 mA for x10 setting
Output Pulse	50 microseconds (µs) wide pulses, user selectable from 1 to 9 pulses, repetition rate user variable between 1 and 9.9 ms	50, 100, 200, 500, 1000, 2000 microseconds (µs) wide, single pulse	50, 100, 200 microseconds (µs) wide, single pulse
Compliance	Max current 1.5A peak	Continuously variable from <100V to 400V	Continuously variable from <100V to 400V

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Parameter	Predicate Device D185	DS7A	DS7AH
Over stimulation protection	Safety trip out circuit operated by the energy of the output; limits the number of pulses available in one train and inhibits re-triggering outside safe limits Visual warning given to operator if an attempted stimulus is outside operational limits	Safety trip out circuit operated by the energy of the output; monitors pulse width and current and inhibits re-triggering outside safe limits Visual warning given to operator if an attempted stimulus is outside operational limits	Safety trip out circuit operated by the energy of the output; monitors pulse width and current and inhibits re-triggering outside safe limits Visual warning given to operator if an attempted stimulus is outside operational limits
Output Connections	4 mm shrouded sockets (red and black) on 3/4" centres Red socket goes positive with reference to black socket	Same	Same
Stimulus initiation	Front panel push button, foot switch or external electrical trigger signal	Same	Same
External trigger input	+3 to 15 V +ve edge TTL compatible	Same	Same
Construction	Non-conductive plastic case, aluminium front and rear panels fully laminated with single piece polycarbonate labels	Same	Same
Application of standards	Compliant with EN 60601-1, EN 60601-1-2, and the relevant parts of EN 60601-2-40	Same	Same

Substantial equivalence

The Digitimer DS7A and the Digitimer DS7AH are substantially equivalent in terms of safety and effectiveness to the Digitimer D185 (510(k) #K020400).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2005

Digitimer Ltd.
c/o Mr. Harry J. Benedict
Official Correspondent
MEPs-LLC
One East Broward Boulevard, Suite 700
Fort Lauderdale, Florida 33301

Re: K051357
Trade/Device Name: Digitimer DS7A and DS7AH Constant Current High Voltage Stimulators
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: II
Product Code: GWF
Dated: August 8, 2005
Received: August 9, 2005

Dear Mr. Benedict:

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.

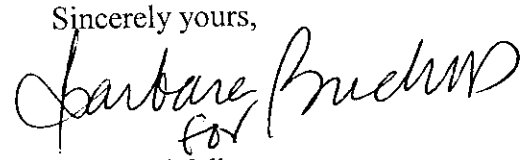
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K051357**

Device Name: **DIGITIMER DS7A and DS7AH CONSTANT CURRENT HIGH VOLTAGE STIMULATORS**

Indications for use:

The DS7A and DS7AH are stimulators intended for use during neurological monitoring and assessment in a clinical environment.
They are intended for use by trained personnel either competent to apply appropriate stimuli or under the supervision and instruction of one who is.

Prescription Use __✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Barbara Buehler

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

510(k) Number K051357