March 6, 2018

Digitimer Ltd.
John Smale
Managing Director
37 Hydeway
Welwyn Garden City, Hertfordshire, AL7 3BE, UK

Re: K172381
Trade/Device Name: Digitimer DS7AP Constant Current Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: January 3, 2018
Received: January 8, 2018

Dear John Smale:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172381

Device Name
Digitimer DS7AP Constant Current Stimulator

Indications for Use *(Describe)*

The Digitimer DS7AP Constant Current Stimulator is indicated for use as an adjunct in the treatment of high and low anorectal malformations by helping in the identification of the striated muscles to be used in anal reconstructions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter:	Digitimer Ltd
Submitter's Address:	37 Hydeway, Welwyn Garden City, Hertfordshire, AL7 3BE, UK
Contact person:	John Smale Managing Director +44 (0)1707 328347
Date Summary Prepared:	December 31, 2017
510(k) Number:	k172381
Device Name:	DS7AP Constant Current Stimulator
Device Common Name	Powered Muscle Stimulator; CFR890.5850
Device Classification:	Class II
Predicate Device:	Radionics Pena Muscle Stimulator PS-1 - 510(k) K980448
Indications for Use:	The Digitimer DS7AP Constant Current Stimulator is indicated as an adjunct in the treatment of high and low anorectal malformations by helping the identification of striated muscle to be used in anal reconstructions.
Device Description:	The DS7AP Constant Current Stimulator has been specially designed to meet the requirements of pediatric surgeons who need a reliable and easy to use muscle locating stimulator when carrying out the Peña, "Pull-through" or posterior sagittal anorectoplasty (PSARP) anorectal reconstruction technique. **Intended Patient Population** The reconstruction surgeries, for which the DS7AP is intended, are typically carried out in young children (<3 years). **Intended Part of the Body to be Interacted With** The DS7AP is used in the treatment of anorectal malformations by helping the identification of striated muscles to be used in anal reconstructions. **Intended User Profile** The intended User is a specialist clinician trained in Neurophysiological studies, or a surgeon trained in the specialist reconstruction surgeries for which the DS7AP is intended. They are likely to be either a doctor with neurology training or a Clinical Neurophysiological Scientist for which the training requirement recommendations (in the UK) is 4 years of undergraduate study.

	Intended Conditions of Use The DS7AP is intended for static table top use in a clinical environment, typically a neurosurgery operating theatre.
Electrical Performance:	Power: 100-120V or 200-240V (externally selected), 47-63Hz, 12VA. Classification: IEC 60601-1 Class 1 with Type BF applied part. Power: Push rod On/Off switch. Pulse duration: LO (200µs) or HI (500µs), two position rotary switch. Current: 0-100mA, continuously adjustable dial. Compliance voltage: 100V. Output frequency: 50Hz. Output enable: Toggle Switch (On is Up, Off/Reset is down). Output connections: 4mm shrouded, touch-proof sockets (red and black) on 3/4" centers. Footswitch connection rear panel 3.5mm mono jack socket (for optional D185-FS1 contact closure footswitch).
Mechanical Performance:	Size: 10" x 4" x 10" (255 x 100 x 225 mm) - d x h x w 10.6" x 4.33" x 9" (270 x 110 x 225 mm) - d x h x w - over controls and feet. Weight: 4.5 pounds (2.1 kg) approx.
Temperature:	Operating Range 50°F to 104°F (10°C to 40°C) 30 to 75%, non-condensing Storage Range -40°F to 158°F (-40°C to 70°C) 10 to 100%, non-condensing Transport Range -40°F to 158°F (-40°C to 70°C) 10 to 100%, non-condensing
Other:	Power: 115V or 230V @ 50/60 Hz Rating: <30 VA Case Material: UL94 V-0 Flame Retardant
Front Panel Indicators:	Power: Green LED, illuminated for power ON. Trigger: Amber LED, illuminated to indicate stimulus trigger is active. Compliance: Amber LED, illuminated if the compliance limit is reached i.e. the current requested cannot be delivered (e.g. due to high resistance between probe tips). Reset/Fault: Amber LED illuminated and latched for sensed over current and at power on.
Installation	The DS7AP does not need installation by Digitimer personnel as they are supplied with comprehensive instructions and are easy to set up & operate.

Footswitch: The footswitch is a medical grade foot switch that is sealed to IP68 so as to meet all the requirements of IEC 60601-1 for use within operating theatres.

Disposable Precision Bipolar Stimulation Probe:

Available in packs of 10 probes, the Technomed Neurosign Precision Bipolar Probe is an ideal single-use stimulation probe. The probes are fitted with 1.5mm DIN 42 802 connectors and need to be used in conjunction with our 2m long **D185-HB4-2m Output Extension Cable**

The Precision Bipolar Probe has been cleared for marketing by the FDA under number k050325. This included an evaluation of biocompatibility

Technological Characteristics:

Characteristic:	**Subject Device: DS7AP**	**Predicate Device: PS-1**
510(k) number	K172381	K980448
Intended Use	Used to identify striated muscle in the treatment of high and low anorectal malformations	Used to identify striated muscle in the treatment of high and low anorectal malformations
Indications for Use	The DS7AP is indicated for use of as an adjunct in the treatment of high and low anorectal malformations by helping in helping in identification of the striated muscle to be used in anal reconstructions	The PS-1 is indicated for use of as an adjunct in the treatment of high and low anorectal malformations by helping in helping in identification of the striated muscle to be used in anal reconstructions
Classification	Class II	Class II
Product Code	IPF	IPF
Regulation Number	CFR 890.5850	CFR 890.5850
Power Source	Supply Mains (115/230V; 50/60Hz)	Primary battery (PP3 / 1604)
Number of Output Channels	One	One
Output Control	Constant Current	Constant Current
Firmware Control?	No	No
Automatic Overload Trip?	Yes	No
Compliance with 21 CFR 898?	Yes	No
Weight	4.85lb	1.52lb
Dimensions (wxhxd)	8.6”x4.4”x 9.9”	3.75”x3.5”x6.25”
Housing Materials	Thermo-plastic with metal front and rear panels	Thermo-plastic with metal front and rear panels
Waveform	Pulsed mono-phasic	Pulsed mono-phasic
Waveform Shape	Rectangular	Rectangular
Maximum Output Voltage[1]	56V @ 500Ω 126V @ 2kΩ 126V @ 10k Ω	122V @ 500Ω 220V @ 2kΩ 224V @ 10k Ω

Characteristic:	Subject Device: DS7AP	Predicate Device: PS-1
Maximum Output Current[2]	112mA @ 500Ω 63mA @ 2kΩ 13mA @ 10k Ω	244mA @ 500Ω 110mA @ 2kΩ 22mA @ 10k Ω
Pulse Width	200µs / 500µs	175µs
Pulse Frequency	50Hz	65Hz
Maximum Phase Charge	56µC @ 500Ω	42.2µC @ 500Ω
Maximum Current Density[3]	0.127mA/cm^2 @ 500Ω	0.117mA/cm^2 @ 500Ω
Maximum Power Density[3]	0.191W/cm^2 @ 500Ω	0.161W/cm^2 @ 500Ω
Notes: 1. Peak voltage, dependent upon the current control setting and the fixed load resistance. 2. Peak current, limited by the maximum compliance voltage available. 3. Figures assume use of the G3604-00 Disposable Probe for both devices.		

Different Technological Characteristics:

The subject device and the predicate differ in the power source used, with the subject using mains power and the predicate using batteries.

The power supply of the subject device is identical to that of the Digitimer DS7A/AH Constant Current Stimulators, which are approved for marketing under number k051357.

Nonclinical Tests:

Nonclinical tests have been based on the compliance with the following international standards.

Standard Utilized	FDA Consensus Standard	Comments
EN 60601-1:2006	AAMI ANSI ES60601-1:2005/(R) 2012 and A1:2012	Differences covered by additional testing
EN 60601-1-2:2007	IEC 60601-1-2:2007	Same
IEC 62366-1:2015	AAMI ANSI IEC 62366-1:2015	Same
ISO 14971:2007	ISO 14971:2007	-
EN 60601-2-10:2015 + A1:2016	IEC 60601-2-10:2012	-
FDA Guidance Document for Powered Muscle Stimulator 510(k)	None	Comparison of DS7AP and predicate device

Clinical Tests: No clinical tests are required for this submission

Conclusions of Nonclinical & Clinical Tests:

The DS7AP Constant Current Stimulator meets the requirements of the non-clinical testing defined above.

The intended use and the technological characteristics have also been compared in detail with the predicate device and found to be substantially equivalent.

No clinical tests were required to support this 510(k)