K082614

510(k) Summary
(per 21 CFR 807.92)

MAR - 6 2009

I. Applicant

Laborie Medical Technologies, Inc.
6415 Northwest Drive, Unit 10
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Date Prepared: July 30, 2008

II. Device Name

Proprietary Name:	Laborie EVOX Electro Diagnostic Device
Common/ Usual Name:	
Classification Name:	Stimulator, Electrical, Evoked Response
Regulation Number:	882.1870 and 882.1550
Product Codes:	GWF, JXE
Classification:	2
Classification Panel:	Neurology

III. Predicate Device

The Laborie Evo Electro Diagnostic Device is substantially equivalent to the Dantec Keypoint K944547 and the Cadwell K962455 in its intended use and in its technical characteristics as well as the safety and effectiveness of the device as a diagnostic tool.

IV. Intended Use of the Device

The EVOX Electro Diagnostic Device is intended for the testing of sacral reflexes, pudendal nerve terminal motor latency (PNTML) studies, electromyography (EMG), and cerebral pudendal somatosensory evoked potential (SEP).

V. Description of the Device

The EVOX Electro-Diagnostic Device utilizes Laborie Urodynamic equipment 510(k) exempt under section § 876.1620 or with another microprocessor that is compatible with the required capability.
The Laborie EVOX Electro Diagnostic Device will help diagnose and perform evaluation tests for urinary and fecal incontinence as well as other neurological and physiological assessment, including:
Pudendal Nerve Terminal Motor Latency with St Marks Electrodes
Anal Sphincter CN EMG
Cerebral Pudendal Somatosensory Evoked Potential

Sacral Reflexes
Calculations will include: latency, peak, duration, conduction velocity and area.

The equipment includes the Evox Electro-diagnostic Software and the hardware required to perform the stated tests which include:

- Laborie 94-based Hardware with Integrated Electrodiagnostic Stimulation
- Ring/Bar Stimulation Electrodes
- Needle/Cup/Patch EMG/ECG Electrodes
- St. Mark's Electrode and Cable
- EMG/ECG Cabling

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Summary of the Technical Characteristics

Components and or Features	Laborie EVO	Predicate Device- Dantec KeypointK944547	Cadwell Sierra/Cadwell 6200A K962455
Safety	Complies with IEC 60601-1 standards and IEC 60601-2-10 standards.		Designed to comply with requirements of UL 544; Isolated patient connection IEC 601-1: Type BF
Electrode inputs	2 Electrode Inputs: Bar, Ring, Needle, Cup or St. Mark Electrodes.	5-pin Din connectors	4 Buffered electrode inputs with separate active and reference 1.5 mm touch proof connectors or 5 pin DIN connector
Isolated Ground Connections	There is main power supply double/reinforced isolation between the UDS system and Live/Neutral/ Earth, which act as another isolation barrier.		2 Connections
Isolation Mode Rejection	No isolation amplifier is used. For IMRR instrumentation amplifier is used.		> 150dB
Common Mode Rejection	100dB	> 100 dB	90dB
Sensitivities	2,100 MicroV/div	.5µV to +/- 20,00 µV/div	2,5,10,20,50,100,200,500 Micro V/div; 1,2,5,10,20 m V/div.
Noise	6 microV peak to peak		2 micro V peak to peak (10Hz to 10kHz)
Input Impedance	> 1,000 Mohms (common mode)		>1,000 Mohms (common mode)

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Notch Filter	50-60Hz	50-60 Hz	50-60Hz
Low-cut Filters	FIR filter Selectable at 10, 50, 100, 300, 500, 1000, 2000, 3000, 4000 Hz	Filter selectable at 20, 50, 100,200,300,500,1000, 2000,3000,5000, 10000 Hz	1-2 pole filter Selectable at 0.04, 0.1, 1, 3, 10, 30, 100, 500 Hz
High-cut filters	N/A	Filter selectable at 0, 0.1,0.2,0.5,1,2,5,10, 20,50,100,200,500, 1000,2000,3000 Hz	2-pole filter Selectable at 30, 50,100,200,300,500 Hz; 1, 1.5,2,3,5,10,15kHz
Common recording reference input	1 input	1 input	1 input
Temperature probe input	N/A		20 to 45°C
Stimulation Signal	Monophasic Current controlled for a maximum of up to 100mA and 270 V	Biphasic and monophasic	
Signal Capture-EMG	+/- 1mV range	+/-5μV to +/- 20,000 μV range available +/-1 to 50mV used for test	
Signal Capture-EEG	+/- 20μV range	+/-5μV to +/- 20,000 μV range available +/-5 μV to 50 μV used for test	
Multiple Sample Acquisition for Accuracy	Yes	Yes	Yes
Event Marking	Yes	Yes	Yes
Software Data Analysis	Yes	Yes	Yes
Report Generation & Data Storage	Yes	Yes	Yes
Patient Info	Yes	Yes	Yes

VI. Testing

Bench studies have confirmed the efficacy of the EVOX Electro Diagnostic Device. Safety testing included electrical safety testing and electromagnetic compatibility testing to recognized standards.

VII. Safety & Effectiveness

The Laborie EVOX Electro-Diagnostic Device is substantially equivalent to the Dantec Keypoint and the Cadwell Sierra.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Laborie Medical Technologies, Inc.
% Ms. Barbara Mornet
Regulatory Affairs Deputy
400 Avenue D, Suite 10
Williston, VT 05495-7828

MAR - 6 2009

Re: K082614
Trade/Device Name: Laborie EVOX Electro Diagnostic Device
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: II
Product Code: GWF, JXE
Dated: January 23, 2009
Received: January 26, 2009

Dear Ms. Mornet:

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 Biometric's (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 toll-free number (800) 638-2041 or (240) 276-3150 or 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

Indications for Use

510(k) Number (if known): K082614

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