JUN 28 2011

510(k) Summary – K110752
Highland Instruments CES and TUS Instrument Holder

Submitter:	Highland Instruments 395 Broadway Apartment R4d Cambridge MA Phone: 617-504-6031 Fax: 617-945-7453
Contact Person:	Leo Basta NorthStar Biomedical Associates 755 Westminster St., Unit 120 Providence, RI, 02903 Phone: 617.834.9866 lbasta@northstarbiomedical.com
Date Prepared:	May 25, 2011
Trade Name:	Highland Instruments CES and TUS Instrument Holder
Regulation Name:	Ultrasonic pulsed doppler imaging system and accessories and Operating room table and attachments
Classification Number:	21 CFR 892.1570, 878.4950
Product Code:	ITX, BWN
Predicate Devices:	TCD 100M/Marc 600 Spencer Probe Fixation System - K002533, found substantially equivalent on August 30, 2000. Civco Assist Positioning Arm System with Ultrasound Transducer Holder - Class I 510(k) Exempt.
Device Description:	The Highland Instrument CES and TUS Instrument Holder is intended to position and hold in position the ultrasound probe of a Transcranial Ultrasound device while at the same time assisting in maintaining the position of electrodes used with a Cranial Electrotherapy Stimulator (CES) device and keeping the electrode lead wires free

	from entanglement and otherwise free from being disturbed by the patient. The Highland Instrument Holder allows for a physician to utilize a commercially available CES device while simultaneously observing/measuring cerebral regional blood flow in discreet areas of the brain. It further allows the physician to utilize a commercially available CES device while imaging the brain with transcranial ultrasound imaging probes that do not contain the Doppler option.
Intended Use:	The Highland Instruments CES and TUS Instrument Holder is intended for use in assisting holding and securing commercially available CES electrodes and diagnostic Transcranial Ultrasound System Probes in the desired position on the patient's head.
Functional Testing:	Descriptive information, laboratory bench testing and a biocompatibility assessment were provided to demonstrate the device meets is design specifications, performs as intended, and is safe for its intended use. Specifically, the device introduces no new materials from consumer products currently on the market. In addition, testing to demonstrate the ability of the device to position and hold a variety of transducers and lead wires in position was performed.
Summary of Substantial Equivalence:	The design, intended use, and principles of operation of the Highland Instrument Holder device are substantially equivalent to those of the predicate devices cited above. Substantial equivalence is based upon descriptive characteristics of the various cited predicate devices and upon the testing conducted to demonstrate that the subject device performs as intended and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Highland Instruments
% Mr. Leo Basta
Owner
NorthStar Biomedical Associates
755 Westminister St., Unit 120
PROVIDENCE RI 02903

JUN 28 2011

Re: K110752
Trade/Device Name: Highland Instruments CES and TUS Instrument Holder
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX and BWN
Dated: May 25, 2011
Received: May 31, 2011

Dear Mr. Basta:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K110752

Device Name: Highland Instruments CES and TUS Instrument Holder

Indications for Use:

The Highland Instruments CES and TUS Instrument Holder is intended for use in assisting holding and securing commercially available CES electrodes and diagnostic Transcranial Ultrasound System Probes in the desired position on the patient's head.

Prescription Use: X AND/OR Over-The Counter Use: _____
(Per 21 CFR 801 Subpart D) ..... (Per 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)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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