DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 10, 2014

Hemedex Inc.
Dean Honkonen
VP, Regulatory Affairs and Quality Assurance
222 3rd St Suite 0123
Cambridge, Massachusetts 02142

Re: K141869
Trade/Device Name: QFlow 500 Titanium Bolt Kit, Quad Lumen
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM, HBG
Dated: July 8, 2014
Received: July 14, 2014

Dear Mr. Honkonen,

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

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)*
K141869

Device Name
QFlow 500 Titanium Bolt Kit, Quad Lumen

Indications for Use *(Describe)*
The Hemedex Cranial Bolt is designed to achieve cranial access and to introduce and secure one to four sensors in place for intracranial monitoring.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

HEMEDEX QFLOW 500™ TITANIUM BOLT KIT

510K Summary

Submitter's Name and Address

Hemedex, Inc.
222 Third Street, Suite 0123
Cambridge, MA 02142

Date

October 9, 2014

Contact Person

Dean Honkonen
VP, Regulatory Affairs and Quality Assurance
Telephone (617) 577-1759
Fax (617) 577-9328

Name of Device

Proprietary Name:	QFlow 500™ Titanium Bolt Kit, Quad Lumen
Common Name:	Intracranial Bolt
Classification Name:	Intracranial pressure monitoring device
Product Codes:	GWM, HBG
Regulations:	882.1620, 882.4300
Class:	II
Panel:	Neurology

Statement of Substantial Equivalence

The QFlow 500™ Titanium Bolt Kit is substantially equivalent in intended use, function and design to the Hemedex Single and Dual Lumen Cranial Bolts (K032337), as well as the Integra Licox Brain Monitoring System, PN IM1, IM2, IM3 (K002765).

Purpose

This submission covers design changes to predicate device cranial bolt K032337 that adds two lumens to the dual lumen bolt for a total of four lumens. New kit components are added to accommodate the additional sensors and for ease of use.

Device Description

The QFlow 500™ Titanium Bolt Quad Lumen Kit is used to achieve cranial access and to introduce and secure up to four sensors in place for intracranial monitoring. The kit contains a cranial bolt, drill bit, scalpel, sensor introducer with stylet, Touhy Borst fittings and connectors. The cranial bolt contains four lumens with its primary materials being titanium, polyphenylsulfone, polyvinyl chloride and polycarbonate. The primary materials of the sensor introducer are polyether block amide and polycarbonate. The primary materials of the other components in the kit are stainless steel, titanium nitride, acrylonitrile butadiene styrene, polyphenylsulfone, polyvinyl chloride and polycarbonate.

Indications for Use

The Hemedex Cranial Bolt is designed to achieve cranial access and to introduce and secure one to four sensors in place for intracranial monitoring.

The QFlow 500™ Titanium Bolt Quad Lumen indications for use differ from predicate devices K032337 and K002765, in that the Quad Lumen Bolt allows for one to two additional sensors to be inserted. This difference does not change the use of the device as it is still used to introduce and secure sensors in place for intracranial monitoring. The Quad Lumen Bolt improves safety and effectiveness as in cases were more than two sensors are to be placed in a patient, only one burr hole of 5.3 mm in diameter is necessary. Currently, in the case where the physician decides to place four sensors, two burr holes must be drilled for the placement of two dual lumen bolts, or a three lumen bolt combined with a single lumen bolt. Two burr holes drilled into the patient's skull increase the risk of infection and trauma to the patient. Predicate device K002765, Integra Licox Brain Monitoring System, allows for up to three devices to be inserted through one burr hole, requiring a second burr hole and single lumen bolt to be inserted, thus increasing the risk to the patient.

Comparison of Technological Characteristics

	Hemedex Quad Lumen Intracranial Bolt	Hemedex Intracranial Bolt K032337	Integra Licox Brain Oxygen Monitoring System K002765 (P/N IM1, IM2, IM3)
Indications for Use	The Hemedex Cranial Bolt is designed to achieve cranial access and to introduce and secure one to four sensors in place for intracranial monitoring.	The Hemedex Single and Double Lumen Bolts are designed to achieve cranial access and to introduce and secure a sensor in place for intracranial monitoring.	The Licox measures intracranial oxygen and temperature and is indicated as an adjunct monitor of trends of these parameters, indicating the perfusion status of cerebral tissue local to the sensor placement. Licox systems values are relative within an individual and should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern.
Components	Titanium Bolt Bolt wing Compression fitting (cap, body, gasket and washer) Luer tubes Cap, Non-vented, Male Luer Lock Extension fitting Stylet Introducer Drill bit Hex wrench Scalpel	Stainless steel Bolt with wing shape Compression fitting (cap, grommet and washer) Piercing device Cap, Non-vented, Male Luer Lock Sealing Washer Stylet	Stainless steel Bolt Bolt wing Compression fitting (cap, grommet and washer) Luer tubes Stylet Introducer Drill Bit Hex Wrench Piercing needle
Configuration	Quadruple Lumen	Single and Double Lumen	Single, Double & Triple lumen
Bolt Size Length	4.7”	2.0”	6”
Burr Hole Diameter	0.209” (5.3 mm)	0.209” (5.3 mm)	0.209” (5.3 mm)
Compression Fitting Size	ID- 9 F (0.118”)	ID – 4 F (0.050”)	ID – 4 F (0.050”)
Sterilization	Ethylene Oxide	Ethylene Oxide	Gamma Irradiation

Performance Testing

Bench testing was conducted to demonstrate that this device meets the requirements of its intended use and meets the specified performance criteria. Bench testing performed was as follows:

Test	Results	Conclusion
Torque required to insert the cranial bolt	7 - 8 in-lbs maximum torque required	Easily inserted. Met the predetermined specification
Axial tension required to pull the cranial bolt out	Greater than 40 lbf	Acceptably secured in the bone. Met the predetermined specification
Torque required to tighten the Touhy Borst compression cap to seal the sensors	Less than 1 in-lb torque required	Easy to secure the sensors. Met the predetermined specification
Tension required to pull the sensors out of the Touhy Borst	Approximately 1.3 lbf	Sensors secure. Met the predetermined specification
Leak testing	No leaking at 185 mm Hg pressure for 14 days	Easily meets the predetermined sealing specifications
Axial tensile strength of the “pig tails”	19 - 37 lbf depending on pigtail diameter	Strong connections. Met the predetermined specification
Axial tensile strength of the introducer	3.7 - 4.4 lbf	Acceptable. Met the predetermined specification
Axial tensile strength of the pigtail extension	16.6 - 20.6 lbf	Strong connections. Met the predetermined specification
Drill bit dimensional and cutting functionality	Burr hole diameter 0.209” Easily cut through bone	Easy to create the correct size burr hole. Strong connections. Met the predetermined specification

Bench testing was also conducted to demonstrate that this device is substantially equivalent or better than predicate devices K032337, K002765 and a reference device

K992591. The tests selected assess the performance of the devices with regards to their interaction with the patient and user. Bench testing performed was as follows:

Test	Results	Conclusion
Torque required to insert the cranial bolt	The Hemedex Quad Lumen Bolt required 38% to 64% less in-lbs of torque to fully insert, depending on the predicate or reference device	Substantially equivalent or better than the predicate & reference devices
Axial tension required to pull the cranial bolt out of the skull	The Hemedex Quad Lumen Bolt pull out force was greater than 40 lbf. The predicate and reference devices could not reach the 40lbf threshold without incurring damage.	Substantially equivalent or better than the predicate & reference devices
Leak testing	The bolts were tested at increasing intervals of insertion replicating different skull thicknesses at 185 mm Hg pressure. In all cases the Hemedex Quad Lumen Bolts incurred less leaking.	Substantially equivalent or better than the predicate & reference devices
Drill bit dimensional and cutting functionality	The Hemedex Burr hole diameter 0.209" meets specification. Predicate (K002765) and reference device specifications are unknown. All the tested drill bits easily cut through bone. Depth collars remained secure.	Substantially equivalent to the predicate & reference devices

Conclusion

The Hemedex QFlow 500^{TM} Titanium Bolt Kit, Quad Lumen is substantially equivalent to or better than the predicate devices.