OCT 2 1 2003 K032337 (pg 1 of 1)

510K Summary of Safety and Effectiveness

1. Sponsor Name:

   Hemedex, Inc.
   222 Third Street, Suite T123
   Cambridge, MA 02142
   USA

2. Device Name:

   Hemedex Single Lumen Cranial Bolt
   Hemedex Double Lumen Cranial Bolt

3. Identification of Predicate or Legally Marketed Devices:

   Codman Skull Bolt (K992591)
   Codman Intracranial Bolt (K974088)
   Integra Licox Brain Monitoring System (K002765) Part Number IM1, IM2, IM3
   Codman Disposable ICP Kit with Stainless Steel Screw Catalog No. 80-1194

4. Device Description:

   The Hemedex Cranial Bolts are stainless steel threaded cranial access devices with standard tuohy borst compression fittings.

5. Intended Use:

   The Hemedex Cranial Bolts are designed to achieve cranial access and to introduce and secure a sensor in place for intracranial monitoring.

Comparison of Technological Characteristics

The Hemedex Cranial Bolts and the predicate devices use identical technology and materials.

7 Performance Testing

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 2003

Hemedex, Inc.
c/o Ms. Debbie Iampietro
QRC Consulting
7 Tiffany Trail
Hopkinton, Massachusetts 01748

Re: K032337
Trade/Device Name: Hemedex Cranial Bolt
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: July 28, 2003
Received: July 31, 2003

Dear Ms. Iampietro:

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 (301) 594-4659. 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,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032337

Device Name: Hemedex Cranial Bolt

Indications For Use:

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.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark N Milkerson

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

510(k) Number K032337