OCT 31 2002

510(k) Summary
(*per 21 CFR807.92*)

K022638

Neurorecovery™ Ventricular Catheter & Main Valve Assembly Kit

1. APPLICANT

Neurorecovery™, Inc.
325 Queen City Avenue
Tuscaloosa, AL 35401

Contact Person: Landon C. G. Miller; JD, RPA, MSA, BA
Telephone: (205) 345-8606

Date Prepared: August 7, 2002

2. DEVICE NAME

Proprietary Name:	Neurorecovery™ Ventricular Catheter & Main Valve Assembly Kit
Common/Usual Name:	Ventricular Catheter and Accessories
Classification Names:	Ventricular Catheter Intracranial Pressure Monitoring Accessories

3. DEVICE CLASSIFICATION

Ventricular Catheter (21 CFR 882.4100; ProCode: HCA) and Intracranial Pressure Monitoring Accessories (21 CFR 882.1620; ProCode: GWM) have been classified as Class II devices.

4. PREDICATE DEVICES

- Codman EDS II (K902257) Johnson & Johnson Professional, Inc.
- Heyer-Schulte NeuroCare External Drainage Management System (K972994) *[now believed to be MiniTorr CSF Drainage Systems marketed by Integra LifeSciences]*

5. DEVICE DESCRIPTION

The Neurorecovery™, Inc., Neurorecovery™ Ventricular Catheter & Main Valve Assembly Kit consists of legally marketed ventricular catheter, stylet, trocar, valves, tubing, associated connectors, caps, check-valves, needle-free valve, and stopcocks.

6. INTENDED USE

The Neurorecovery™, Inc., Neurorecovery™ Ventricular Catheter & Main Valve Assembly Kit is designed to be used for external monitoring of intracranial pressure (ICP), cerebrospinal fluid (CSF) sampling, and CSF drainage from the lateral ventricles of the human brain. The Main Valve Assembly is designed to facilitate the monitoring, sampling, clearing, and drainage function in an aseptic manner.

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Neurorecovery™, Inc., Neurorecovery™ Ventricular Catheter & Main Valve Assembly Kit is equivalent to cited predicate devices based on its indications for use, design, materials, and operational characteristics. Neurorecovery™, Inc., believes that differences between devices are minor and raise no new issues of safety or effectiveness.

8. PERFORMANCE TESTING

Testing submitted in the 510(k) demonstrates that the Neurorecovery™ Ventricular Catheter & Main Valve Assembly Kit complies with specifications for biocompatibility, sterility, and functional performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2002

Neurorecovery, Inc.
c/o Medical Device Consultants, Inc.
Rosina Robinson
Senior Staff Consultant
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K022638
Trade/Device Name: Neurorecovery™ Ventricular Catheter and Main Valve Assembly Kit
Regulation Number: 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: Class II
Product Code: GWM
Dated: August 7, 2002
Received: August 8, 2002

Dear Ms. Robinson:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Miriam C. Provost

for 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): K022638

Device Name: Neurorecovery™, Inc., Neurorecovery™ Ventricular Catheter & Main Valve Assembly Kit

Indications for Use:

The Neurorecovery™, Inc., Neurorecovery™ Ventricular Catheter & Main Valve Assembly Kit is designed to be used for external monitoring of intracranial pressure (ICP), cerebrospinal fluid (CSF) sampling, and CSF drainage from the lateral ventricles of the human brain. The Main Valve Assembly is designed to facilitate the monitoring, sampling, clearing, and drainage function in an aseptic manner.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K022638

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

(Optional Format 1-2-96)