K051599

510(k) Summary (*Per 21 CFR807.92*)
Neurorecovery™
Comprehensive Intracranial Pressure Evaluation and Relief Kit (CIPER™ Kit)

JUL 1 9 2005

1. APPLICANT

Neurorecovery™, Inc.
1649 McFarland Blvd., N., Suite 203
Tuscaloosa, Alabama 35406

Contact Person: Landon C. G. Miller, JD, RPA, MSA, BA
Telephone: (205) 345-0149

Date Prepared: July 11, 2005

2. DEVICE NAME

Proprietary Name:	Neurorecovery™, Inc. (NRI) Comprehensive Intracranial Pressure Evaluation and Relief (CIPER™) Kit
Common/Usual Name:	Intracranial pressure monitoring device and accessories
Classification Name:	Intracranial pressure monitoring device and accessories

3. DEVICE CLASSIFICATION

Intracranial pressure monitoring devices and accessories (21 CFR 882.1620; ProCode: GWM) have been classified as Class II devices.

4. PREDICATE DEVICES

- Medex, Inc. Intracranial Pressure Monitoring Device (K822864)
- Medex, Inc. Transtar Intracranial Pressure Transducer (K020780)

5. DEVICE DESCRIPTION

The Neurorecovery™ Comprehensive Intracranial Pressure Evaluation and Relief Kit (NRI CIPER™ Kit) is composed of many permanently connected components that incorporate a transducer for connection to an ICP monitoring device. The NRI CIPER™ Kit incorporates components of a cleared intracranial pressure monitoring device, an intracranial pressure transducer, and many components of the Neurorecovery™ Main Valve Assembly. The NRI CIPER™ Kit is designed to be used with the Neurorecovery™ Main Valve Assembly. It is provided to the user sterile, non-pyrogenic (fluid path), single use, disposable, and not recommended for reuse of any kind.

6. INTENDED USE

The Neurorecovery™, Inc., Neurorecovery™ Comprehensive Intracranial Pressure Evaluation and Relief Kit (NRI CIPER™ Kit) is intended for single patient use for the measurement of intracranial pressures (ICP) and drainage of Cerebral Spinal Fluid (CSF). It is intended for short term management of patients with increased intracranial pressure.

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The NRI CIPER™ Kit is equivalent to the 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2005

Ms. Rosina Robinson, RN, Med, RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K051599
Trade/Device Name: Neurorecovery™, Inc., Neurorecovery™ Comprehensive Intracranial Pressure Evaluation and Relief Kit (NRI CIPER™ Kit)
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: June 15, 2005
Received: June 16, 2005

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), please contact the Office of Compliance at (240) 276-0115. 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 Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051599

Device Name: Neurorecovery™, Inc., Neurorecovery™ Comprehensive Intracranial Pressure Evaluation and Relief Kit (NRI CIPER™ Kit)

Indications for Use:

The Neurorecovery™, Inc., Neurorecovery™ Comprehensive Intracranial Pressure Evaluation and Relief Kit (NRI CIPER™ Kit) is intended for single patient use for the measurement of intracranial pressures (ICP) and drainage of Cerebral Spinal Fluid (CSF). It is intended for short term management of patients with increased intracranial pressure.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(510(k) Number K051599