K031986

2.0 510(K) Summery of Safety and Effectiveness

FEB 20 2009

Submitter
Name and address: GN Otometrics A/S
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Summery prepared: November 1st, 2008

Amended: January 23, 2009
February 10th, 2009

Device Name:

Common/Usual Name:	Auditory Evoked Potential System
Trade/Proprietary name:	ICS CHARTR EP 200
Classification name:	Stimulator, Auditory, Evoked Response

Predicate devices
The GN Otometrics ICS CHARTR EP 200 is similar to these relevant Chartr products:

ICS Medical Chartr EP system (K960097)
Product Code: GWJ
Regulation Number: 882.1900
Released: February 21st, 1997

ICS Medical Chartr EP and OAE System (K002985)
Product Code: GWJ & EWO
Regulation Number: 882.1900
Released: December 13th, 2000

ICS Medical Chartr EP with ASSR and Chartr OAE System
510(K) Number: K031986
Product Code: EWO
Regulation Number: 882.1050
Released: July 24th, 2003

ICS CHARTR EP 200 differs from the above in the following ways;

- External hardware platform with USB connection to PC
- Does not have ASSR or OAE.
- Minor Software User Interface enhancements

Description

The ICS CHARTR EP 200 is a PC-based system, which consists of software modules for installation on a PC, an isolation transformer, a hardware platform, pre-amp , a mains adapter, stimulation devices and recording devices,

The stimulation and recording devices are connected to the pre-amp, which is connected to the hardware platform, which is connected to the PC via USB cable – no hardware installation inside the PC is required.

Intended Use

The ICS Chartr EP 200 is indicated for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway.

Technological Characteristics

Device Specifications	**ICS Medical Chartr EP 960097 – 2/21/1997**	**ICS Medical Chartr EP and Chartr OAE – K002985 – 12/13/2000**	**ICS Medical Chartr EP with ASSR and Chartr OAE – K031986 – 7/24/03**	***ICS Chartr EP 200 K083399 (this submission)***
Indication for use EP	Indication for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway	Indication for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway	Indication for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway	Indication for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway
Indication for use OAE	Does not have OAE	Indication for the determination of cochlear function in infants, children, and adults which provides information about hearing without subjective response from the individual being tested.	Indication for the determination of cochlear function in infants, children, and adults which provides information about hearing without subjective response from the individual being tested.	Does not have OAE
Accessories EP	Identical	Identical	Identical	Identical
EP Features Included	ALR, AMLR	ALR, AMLR, P300, 40 Hz Test, PediScreen	ALR, AMLR, P300, 40 Hz Test, PediScreen, ASSR	ALR, AMLR, P300, PediScreen
Electrical Safety	Designed to comply with EN 60601-1 (UL 2601)	Designed to comply with EN 60601-1 (UL 2601)	Designed to comply with EN 60601-1 (UL 2601)	Designed to comply with EN 60601-1 (UL 2601)
EMI Compatibility	Designed to comply with EN 60601-1-2	Designed to comply with EN 60601-1-2	Designed to comply with EN 60601-1-2	Designed to comply with EN 60601-1-2
Specifications for electroencephalographs	Designed to comply with EN60601-2-26	Designed to comply with EN60601-2-26	Designed to comply with EN60601-2-26	Designed to comply with EN60601-2-26
Specifications for electromyographs & evoked response	Designed to comply with EN60601-2-40	Designed to comply with EN60601-2-40	Designed to comply with EN60601-2-40	Designed to comply with EN60601-2-40

equipment				
Operating System	Windows 95	Windows 98	Windows XP	Windows XP
Software	16 Bit	32 Bit	32 Bit	32 Bit
Construction type	PC-based system with built-in hardware and peripherals	PC-based system with built-in hardware and peripherals	PC-based system with built-in hardware and peripherals	PC-based system with external hardware platform and peripherals
Power source	Mains	Mains	Mains	Mains
Computer interface	Integrated in computer	Integrated in computer	Integrated in computer	USB cable connection

Safety

The ICS Chartr EP 200 is designed to provide safety to the patient as well as the user and complies with:

- EN 60601-1:1990, UL 60601-1;2003, CAN/CSA-C22.2 NO 601.1-90:1990 Medical Electrical. Part 1: General requirements for safety.
- EN 60601-1-1:2001 Medical Electrical Equipment. Part 1: General requirements for safety. 1. Collateral standard: Safety requirements for medical electrical systems.
- EN 60601-1-2:2001 Medical Electrical equipment. Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.
- EN 60601-1-4: 2000 Edition 1.1 Consolidated Edition, Medical electrical equipment – Part 1-4: General requirements for Safety –collateral Standard: Programable Electrical Medical Systems.
- EN 60601-2-26: 2002 Medical electrical equipment – Part 2-26: Particular requirements for the Safety of electroencphalographs.
- EN 60601-2-40:1998 Medical electrical equipment – Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment.

The ICS CHARTR EP 200 is designed, developed and manufactured according to the following standards:

- ISO 9001:2000 Quality Managements Systems – Requirements.
- ISO 13485:2003 Quality Management Systems – Requirements for regulatory purposes.

Effectiveness

The ICS CHARTR EP 200 is an Auditory Evoked Response device for replacement of an existing product of a technology type that is available and accepted in the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

GN Otometrics A/S
% GN Otometrics North America
Mr. Dan Sansonetti
125 Commerce Drive
Schaumburg, Illinois 60173

FEB 20 2009

Re: K083399
Trade/Device Name: ICS Chartr EP 200
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked response auditory stimulator
Regulatory Class: II
Product Code: GWJ
Dated: January 23, 2009
Received: January 27, 2009

Dear Mr. Sansonetti:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ICS Chartr EP 200

Indications for Use:

The Chartr EP 200 is indicated for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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