



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

November 16, 2015

GN Otometrics  
% Daniel Kamm  
Principal Engineer  
Kamm & Associates  
8870 Ravello Ct  
Naples, Florida 34114

Re: K151504  
Trade/Device Name: ICS Impulse System Model 1085  
Regulation Number: 21 CFR 882.1460  
Regulation Name: Nystamograph  
Regulatory Class: Class II  
Product Code: GWN  
Dated: May 29, 2015  
Received: October 8, 2015

Dear Mr. Kamm:

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,

**William J. Heetderks -S**

for Carlos L. Peña, PhD, MS  
Director  
Division of Neurological  
and Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151504

Device Name

ICS Impulse System Model 1085

Indications for Use (Describe)

The ICS Impulse System Model 1085 is used in the assessment of the vestibular-ocular reflex (VOR) and nystagmus by measuring, recording, displaying, and analyzing eye and head movements.

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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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."*

## 510(K) Summary, 510(k) K15

**Submitter: GN Otometrics A/S**

**Hoerskaetten 9, Taastrup,  
DENMARK DK-2630**

**Registration number: 9612197**

**C/O GN Otometrics North America**

**50 Commerce Dr Ste 180**

**Schaumburg, IL 60173**

**(US) Phone: 847-534-2150**

**(US) Fax: 847-534-2153**

**Contact: Anders Rasmussen, Manager of Research and Development**

**Date Prepared: May 15, 2015**

### **1. Identification of the Device:**

Proprietary-Trade Name: **ICS Impulse Model 1085**

Classification Name: Code GWN, Nystagmograph, Regulation 882.1460

Common/Usual Name: Nystagmograph

### **2. Equivalent legally marketed devices:**

510(k) #	Name of Device	Manufacturer
K061791	Type 1068 ICS Chartr 200 VNG	GN Otometrics
K122550	ICS Type 1085 Impulse	GN Otometrics

- 3. Description of the Device:** The device is a combination of hardware and software. The patient wears a pair of lightweight, tightly-fitting goggles on which is mounted a very small, very light, very fast, USB video camera and a half silvered mirror. This transparent mirror reflects the image of the patient's eye into the camera. The eye is illuminated by a low-level infra-red light emitting diode which is not visible to the patients. A small sensor on the goggles measures the head movement. The whole goggle system is lightweight but it must be secured tightly to the head to minimize goggle slippage. The software records and displays the information obtained during what is known as a "head impulse test" The basic head impulse test starts with the tester standing behind the patient who is wearing the goggles. While the patient is asked to stare at the fixation dot placed on a projection surface in front of them, the tester rotates the patient's head horizontally through a small angle (about 10-20 degrees) in a brief, abrupt and unpredictable manner, varying the direction and the velocity. The goggles collect both head and eye data. The gyroscope measures the velocity of the head movement (the stimulus). The high-speed camera captures the image of the eye. The OTOSuite Vestibular software processes the head velocity data and velocity data for eye movement (the response). Simultaneous displays of the data for head movement and for eye movement allow the clinician to determine if the response is within normal limits or not. The software also records and displays the information obtained during Positional and Oculomotor tests. A Positional test is performed by moving that patient from one position to another position. In the example of Dix-Hallpike, the patient is sitting and the patient's head is turned 45 degrees to one side and then the patient is moved from the sitting position to the supine position. An Oculomotor test is performed by having the patient stare in various directions or under various environments. In the example of Gaze, the patient is sitting and the patient is asked to stare left, right, up, down or center. The Gaze test can be performed with vision or with vision denied. For both Positional and Oculomotor the goggles collect head and eye data. The accelerometer in the small sensor measures where the head is in space. That information is taken and the patient's head position or any movement during testing is displayed in the software. The high speed camera captures the image of the eye. The OTOSuite Vestibular software processes the eye velocity data (the response). The eye movement is

analyzed to determine the slow phase velocities (SPV). The head data is only used during collection to display if the patient’s head is moving and to guide the tester to position the patient’s head appropriately for the test. This is what we refer to as “Head Position Feedback”. Tests where slow phase velocity is measured display the eye position trace and slow phase velocity beats in a graph. In Oculomotor there are 2 tests VOR and Skew Deviation that are not SPV tests. VOR (vestibular ocular reflex) which allows for both visual VOR (VVOR) and VOR suppression (VORS). This test is very similar to the head impulse test but the head movement is slow (0.5 Hz) and small (10 degrees). In VVOR the patient is sitting and the examiner moves the head from side to side (like a sinusoid) while the patient stares at a fixed target. In VORS the patient is sitting and the examiner moves the head from side to side (like a sinusoid) while the patient stares at a moving dot projected from the goggle using one of the lasers. The analysis is similar to head impulse, simultaneous displays of the data for head movement and for eye movement allow the clinician to determine if the response is within normal limits or not. In Skew Deviation (also known as cover test or alternate cover test) the patient is sitting and the tester covers and uncovers. The OTOSuite Vestibular software measures the eye position trace during the cover and uncover environments and displays an average eye position shift.

4. **Indications for Use** (intended use): The ICS Impulse Model 1085 is used in the assessment of the vestibular-ocular reflex (VOR) and nystagmus by measuring, recording, displaying, and analyzing eye and head movements.
  
5. **Safety and Effectiveness, comparison to predicate device.** This device has the same core hardware and software as our K122550 and adds the ability to record nystagmus as in our other predicate K061791. Video camera interface has been changed from firewire to USB. This is not a meaningful difference. A “vision denied” solution (see table below) has been added which is functionally the same as in K061791.
  
6. **Description of Testing:** The device platform (1085) had previously passed UL Electrical Safety testing and EMC testing. Software validation and risk analysis was performed. Biocompatibility testing was successfully performed on the patient contact materials. A clinical analysis based on published literature. The ICS Impulse adequately meets the design requirements and acceptance criteria.

**7. Substantial Equivalence Chart**

<b>Characteristic</b>	GN Otometrics A/S Type 1068 ICS Chartr 200 VNG K061791	GN Otometrics A/S ICS Type 1085 Impulse K122550	GN Otometrics 1068 A/S Type 1085 ICS Impulse
<b>Intended Use</b>	The Focus VNG/ENG is a nystagmograph that is intended to measure, record and display involuntary movements (nystagmus) of the eyeball.	The ICS Impulse System is used in the assessment of the vestibular-ocular reflex (VOR) by measuring, recording, displaying, and analyzing eye and head movements.	The ICS Impulse System is used in the assessment of the vestibular-ocular reflex (VOR) <b>and nystagmus</b> by measuring, recording, displaying, and analyzing eye and head movements.
<b>Product Code</b>	GWN	GWN/LXV	GWN

<b>Characteristic</b>	GN Otometrics A/S Type 1068 ICS Chartr 200 VNG K061791	GN Otometrics A/S ICS Type 1085 Impulse K122550	GN Otometrics 1068 A/S Type 1085 ICS Impulse
<b>Configuration</b>	ICS Chartr 200 VNG consists of a hardware box and VG-40 binocular video goggles. The goggles can record one eye (monocular) or two eye binocular. The ICS Chartr 200 cannot measure head movement	The patient wears a pair of lightweight, tightly-fitting goggles on which is mounted a very small, very light, very fast, <b>firewire</b> video camera and a half silvered mirror. This transparent mirror reflects the image of the patient's eye into the camera. The eye is illuminated by a low-level infra-red light emitting diode which is not visible to the patients. A small sensor on the goggles measures the head movement. The whole goggle system is lightweight but it must be secured tightly to the head to minimize goggle slippage.	The patient wears a pair of lightweight, tightly-fitting goggles on which is mounted a very small, very light, very fast, <b>USB</b> video camera and a half silvered mirror. This transparent mirror reflects the image of the patient's eye into the camera. The eye is illuminated by a low-level infra-red light emitting diode which is not visible to the patients. A small sensor on the goggles measures the head movement. The whole goggle system is lightweight but it must be secured tightly to the head to minimize goggle slippage.
<b>Test Battery</b>	The ICS Chartr 200 is a full VNG system which allows for the following types of tests: Oculomotor, Positional, and Calorics. The system allows for recording of the eye with vision and vision denied. The software includes a slow phase velocity algorithm developed in collaboration with Dr Stockwell.	The ICS Impulse system allows for the following types of tests: recording the eye video and room video as known as Monocular Video Frenzel, and Video Head Impulse Test (vHIT). The system allows for recording of the eye <b>with vision only</b> . The system also allows for recording of the room through the use of a webcam. A monocular video frenzel (only allows recording of the eye and room with no data analysis).	The ICS Impulse system allows for the following types of tests: Monocular Video Frenzel, Video Head Impulse Test (vHIT) Oculomotor and Positional. The system allows for recording of the eye with vision <b>and vision denied</b> . The system also allows for recording of the room through the use of a webcam. A monocular video frenzel (only allows recording of the eye and room with no data analysis). The software includes a slow phase velocity algorithm developed in collaboration with Dr Barin a protégé of Dr Stockwell.

<b>Characteristic</b>	GN Otometrics A/S Type 1068 ICS Chartr 200 VNG K061791	GN Otometrics A/S ICS Type 1085 Impulse K122550	GN Otometrics 1068 A/S Type 1085 ICS Impulse
<b>Photo</b>			
<b>Vision Denied Solution</b>	The VG-40 goggles have a shield that can be opened and closed. 	There was no vision denied solution	The ICS Impulse has a solution with a cup and a patch. The cup adheres to the right (test) eye. The cup has a window that allows the IR camera to see through in order to record eye movement but the patient can not see through it. The patch covers the left (non-test) eye and the patient can not see through it. 
Electrical safety	IEC 60601-1	SAME	SAME
EMC	IEC 60601-1-2	SAME	SAME
Weight	15.2 oz (430 g)	2.1 oz (60g) – goggles	2.1 oz (60g) – goggles
Power Source	USB via PC	SAME	SAME
Computer	Microsoft® XP Professional - Service Pack 2, Vista® Business or Windows 7 Professional 32 or 64 bit	Windows XP 32-bit Professional SP3 or Windows 7 32-bit Professional or Windows 7 64-bit Professional	64-bit: Windows 8 Pro, Windows 7 Professional 32-bit: Windows 8 Pro, Windows 7 Professional
Operator	Trained personnel required	SAME	SAME

**8. Conclusion:** After analyzing software validation, risk analysis, bench testing (including biocompatibility), safety, EMC, and clinical validation (literature review) testing we conclude that the ICS Impulse is as safe and effective as the predicate devices, and has essentially the same indications for use and technology, thus rendering it substantially equivalent to the predicate devices.