February 14, 2025

Natus Medical Denmark Aps
Therese Coffey
Senior Regulatory Affairs Specialist
Hoerskaetten 9
Taastrup, DK-2630
Denmark

Re: K242198
Trade/Device Name: ICS Dizcovery (1091)
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: July 25, 2024
Received: July 26, 2024

Dear Therese Coffey:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242198

Device Name

ICS Dizcovery (1091)

Indications for Use *(Describe)*

ICS Dizcovery is used in the assessment of the vestibular-ocularreflex (VOR) and nystagmus by measuring, recording, displaying, and analyzing eye and head movements.

The 1091 ICS Dizcovery is used in the assessment of patients with complaints of a vestibular nature such as dizziness, disequilibrium, and vertigo. The ICS Dizcovery type 1091 does not treat or diagnose the patient; the diagnosis is determined by the credentialed physician.

ICS Dizcovery system is intended to be used by qualified medical personnel. Typical device users are Neurologists, Ears, Nose, and Throat specialists (ENTs), Audiologists, Physical Therapists, and Technicians supervised by one of the four mentioned typical users. Professionals with knowledge of diagnosing balance disorders. Users are assumed to have prior knowledge of the medical and scientific facts underlying the procedures offered by the ICS Dizcovery system.

The intended patient population are children in the age of 10 to 18 and adults in age range from 18 to 99 years with a complaint of dizziness, balance disorder, or vestibular disease.

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.

ICS® Dizcovery™

510(k) Summary

510(k) Number: K242198

510K Summary

510(k) Number: K242198

Date: 14 February 2025

Submitted By: Natus Medical Denmark Aps
Hoerskaetten 9,
2630 Taastrup,
Denmark

Contact Person: Therese Coffey
Senior Regulatory Affairs Specialist
Natus Medical Incorporated
Tel: +353 (0)91 647400
Fax: +353 (0)91 630050
E-mail: Therese.coffey@natus.com

Proprietary Name: ICS Dizcovery

Common Name: Nystagmograph

Regulation Number: 21CFR882.1460

Classification Name: Nystagmograph

Product code: GWN

Device Class: II

Predicate Device: ICS Impulse 510(k) number: K151504

DEVICE DESCRIPTION:

The ICS Dizcovery device is a portable video-oculography (VOG) device. The device shall be indicated for videonystagmography for the assessment of patients with complaints of dizziness, disequilibrium, and vertigo. It provides an assessment of the vestibular-ocular reflex (VOR) and nystagmus by measuring, recording, displaying, and analyzing eye and head movements.

The ICS Dizcovery is a wearable measurement system in the form of goggles, with built-in cameras and a motion sensor that simultaneously track eye- and head-movement, respectively. The goggles have two cameras that collect the eye movement video. The goggle device is connected to a PC with Otosuite Vestibular PC software (through a USB cable). The Otosuite Vestibular software functions by processing the binocular camera data collection. The collection of eye movement data is analysed to eye movement in respect to various stimuli throughout testing.

The ICS Dizcovery system is made up of the following components:

- A pair of binocular video goggles for testing, controlled through the Otosuite Vestibular PC software
- Otosuite Vestibular PC software for controlling tests, displaying test data for the various tests, reviewing, and printing test results, as well as and managing patients and patient data, users, and test devices.
- A set of Shadeshift® Vision Denied panels; these panels deny the patients vision throughout testing whilst allowing the clinician to continue tracking the eyes in darkness. Vision denied testing is needed throughout the test workflow.
- A set of LCD panels; these automatically shift between dark states to facilitate a user-friendly approach to Skew Deviation testing. This removes the need for manually denying vision of each eye separately with the use of a hand or a paddle.
- A face cushion which inserts into the goggle frame to promote comfort whilst wearing and allow a better fit to face.

Principals of Operation

The ICS Dizcovery system utilizes the following main components and accessories at minimum to achieve its intended use:

- Goggles
- Shadeshift® Vision Denied Panels/ LCD Panels
- Face Cushion

- Otosuite Vestibular PC software

Other accessories available for use with the ICS Dizcovery include:

- Cable Clip
- USB Cable Service Kit
- Head Strap Service Kit
- Hot Mirror Service Kit
- Fixation dots
- Optical Cleaning Cloth
- Cradle
- Carrying Case

The system includes goggles connected to a PC with application software through a USB cable. The patient wears the goggles for testing, the goggles are designed to ensure that they can be secured tightly to the patient's head during testing via a head strap, to prevent them from moving or falling off. A face cushion inserts into the goggle frame so that there is a comfortable fit to the face of the patient and prevention of light from leaking in when testing a patient in vision denied status. The cable connecting to the USB port in the PC has a cable clip to secure to the patient's clothing, this prevents the cable tugging or pulling throughout testing. The patient is presented with a stimulus on a surface (such as a wall) this is projected from the goggles. The patient is asked to track the stimuli with their eyes without moving the head. The goggles have light emitting diodes to light up the eyes and Binocular cameras to record the eye movements. Sliding panels can seal off the patient's eyes from the ambient light when the test requires a darkened environment. An additional set of LCD panels assist in a test that requires movement between dark and light in a short timeframe. These are automatic and driven by the software. The Software will collect the eye movement data in respect to the stimuli generated and analyse the data. A credentialled physician will use this data to make a diagnosis. The device and software include a carry case for mobility and an optional cradle to park the goggles when not in use or between tests.

The ICS Dizcovery system is a non-sterile device intended to be used multiple times per day by the clinician, each appointment would require one use per patient in the above-mentioned clinical environment.

Figure 1 1091 ICS Dizcovery Goggles (for illustration only)

INDICATIONS FOR USE

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

The 1091 ICS Dizcovery is used in the assessment of patients with complaints of a vestibular nature such as dizziness, disequilibrium, and vertigo. The ICS Dizcovery type 1091 does not treat or diagnose the patient; the diagnosis is determined by the credentialed physician.

ICS Dizcovery system is intended to be used by qualified medical personnel. Typical device users are Neurologists, Ears, Nose, and Throat specialists (ENTs), Audiologists, Physical Therapists, and Technicians supervised by one of the four mentioned typical users. Professionals with knowledge of diagnosing balance disorders. Users are assumed to have prior knowledge of the medical and scientific facts underlying the procedures offered by the ICS Dizcovery system.

The intended patient population are children in the age of 10 to 18 and adults in age range from 18 to 99 years with a complaint of dizziness, balance disorder or vestibular disease.

COMPARISON OF TECHNOLOGICAL CHARACTERISITICS WITH THE PREDICATE DEVICE

Both the subject and predicate device operate on the same technological principle; A wearable measurement system in the form of goggles, with built-in camera and motion sensors that simultaneously track eye- and head movement, respectively. The device connects to a computer with Otosuite Vestibular software that analyzes and compares head and eye movement, to assess the vestibulo-ocular reflex, which is an indicator of overall vestibular function. The software functions by automatically detecting the pupil and tracking its horizontal and vertical movement throughout testing.

Specific design changes in the ICS Dizcovery system include the following:

- Replacement of the camera module with two camera modules with better resolution
- Replacement of the static laser module with a movable laser module (freedom laser®)
- Replacement of the Vision Denied cups with Shadeshift® vision denied panels (same functionality, but improved usability)
- Introduction of LCD panels (Improve usability of Skew deviation test)
- Introduction of an onsite serviceable product- replaceable USB cable, Hot Mirror and Head strap (same functionality, improved customer satisfaction)

ICS Dizcovery is similar to the predicate device ICS Impulse in that they both:

- Have the same intended use & indications for use
- Have the same clinical users
- Use the same operating principle
- Have the same software

SUBSTANTIAL EQUIVALENCE TABLE

Specification/ Feature	SUBJECT DEVICE: ICS Dizcovery	PREDICATE DEVICE: ICS Impulse (K151504)	Equivalency (Similarities or Differences)
General			
Indications for use	ICS Dizcovery is used in the assessment of the vestibular-ocular reflex (VOR) and nystagmus by measuring, recording, displaying, and analyzing eye and head movements. The 1091 ICS Dizcovery is used in the assessment of patients with complaints of a vestibular nature such as dizziness, disequilibrium, and vertigo. The ICS Dizcovery type 1091 does not treat or diagnose the patient; the diagnosis is determined by the credentialed physician. ICS Dizcovery system is intended to be used by qualified medical personnel. Typical device users are Neurologists, Ears, Nose, and Throat specialists (ENTs), Audiologists, Physical Therapists, and Technicians supervised by one of the four mentioned typical users. Professionals with knowledge of diagnosing balance disorders. Users are assumed to have prior knowledge of the medical and scientific facts underlying the procedures offered by the ICS Dizcovery system. The intended patient population are children in the age of 10 to 18 and adults in age range from 18 to 99 years with a complaint of dizziness, balance disorder or vestibular disease.	ICS Impulse is used in the assessment of the vestibular-ocularreflex (VOR) and nystagmus by measuring, recording, displaying, and analyzing eye and head movements.	Same- the indication for use statement is expanded to clarify the intended use, the intended users and patient populaton of the device. The additional statement gives clarity to the general use of the device.

Specification/ Feature	SUBJECT DEVICE: ICS Dizcovery	PREDICATE DEVICE: ICS Impulse (K151504)	Equivalency (Similarities or Differences)
Patient population	The intended patient population are children in the age of 10 to 18 and adults in age range from 18 to 99 years with a complaint of dizziness, balance disorder, or vestibular disease.	Patient population are children and adults in age range from 10 years to 99 years.	Similar- Clarification added for patients with a complaint of dizziness, balance disorder, or vestibular disease.
Anatomical sites	The video goggles are placed on the patient's head.	The video goggles are placed on the patient's head.	Same
Intended Users	Neurologists, Ears, Nose, and Throat specialists (ENTs), Audiologists, Physical Therapists, and Technicians supervised by one of the four mentioned typical users. Professionals with knowledge of diagnosing balance disorders.	Neurologists and Ears, Nose, and Throat specialists (ENTs), Audiologists, Physical Therapists and Technicians. Professionals with knowledge of diagnosing balance disorders.	Same
Where used	Hospitals, ENT/Neurology/Audiology Clinics	Hospitals, ENT/Neurology/Audiology Clinics	Same
User interface	PC software	PC software	Same
Interface	USB 3.0 to PC type A	USB 3.0 to PC, type A	Same
System architecture	Wearable measurement system in the form of goggle connected directly to a PC	Wearable measurement system in the form of goggle connected directly to a PC	Same
Technological Characteristics			
Single use Face cushion	ICS Dizcovery has a single use face cushion to secure a proper interface between the goggle and the patients face.	ICS Impulse has a single use face cushion to secure a proper interface between the goggle and the patients face.	Similar – same functionality.

Specification/ Feature	SUBJECT DEVICE: ICS Dizcovery	PREDICATE DEVICE: ICS Impulse (K151504)	Equivalency (Similarities or Differences)
Power supply	Device is powered through USB (5 V DC, 900 mA)	Device is powered through USB (5 V DC, 500mA)	Similar- See substantial equivalence discussion
Camera system	Number of sensors: 2 Resolution: 1280 x1024 pixels	Number of sensors: 1 Resolution: 320 x 240 pixels	Similar- See substantial equivalence discussion
Data Management	Saved in the PC SW	Saved in the PC SW	Same
Report	The user can generate report from the PC SW	The user can generate report from the PC SW	Same
Specific Technological Characteristics			
Eye recording	Simultaneous and individual recording of both left and right eye	Recording of only right eye	Similar- See substantial equivalence discussion
Eye range tracked	± 30° Horizontal; ± 25° Vertical	± 30° Horizontal; ± 25° Vertical	Same
Oculomotor stimuli	Static and Moving Laser projection from inside the goggle	Static Laser projection from inside the goggle.	Similar- See substantial equivalence discussion
Stimuli Viewing Distance	Stimuli presented at 1 to 2 meters from the goggle.	Stimuli presented at 1 to 2 meters from the goggle.	Same
Standards met			
Applied Standards	All relevant Electrical Safety and Biocompatibility standards	All relevant Electrical Safety and Biocompatibility standards	Same (see below for a detailed list of applied standards)

SUBSTANTIAL EQUIVALENCE DISCUSSION:

The subject device has the same intended use, indications for use, clinical users & operating principle as the predicate device. The products are also similar in terms of technological characteristics as both measure record, display, and analyze eye and head movements.

The ICS Dizcovery system represents an upgrade to the predicate ICS Impulse system hardware to improve usability and capability. The ICS Dizcovery system incorporates binocular and monocular video recording and playback, alongside an in-built moveable laser (freedom laser®), compared with the predicate device (ICS Impulse) which incorporates monocular video recording and playback, alongside an in-built static laser. While the ICS Impulse (predicate device) has a single camera that measures and records the movement of the right eye only, the ICS Dizcovery (subject device) has two-camera's that measure and record the movement of both left and right eye simultaneously as well as individually, providing a comprehensive assessment of the left eye as well as the right eye.
The movable laser (freedom laser®) utilised for the ICS Dizcovery enables improved usability by allowing the clinician to test using a moving stimulus rather than a static stimulus (as utilized in the predicate device ICS Impulse). This upgraded mechanism prevents the need to move the patients head throughout testing.

The ICS Dizcovery system, including accessories was independently tested to applicable biocompatibility, Safety, EMC, ANSI S3.45 2009 (R2019), Usability, and Software lifecycle standards and demonstrate the subject device is as safe and effective as the predicate device. Reliability testing was also conducted on the ICS Dizcovery device and accessories by a third party.

Design Verification & Validation activities were performed on the subject device and all tests were verified to meet the required acceptance criteria. The performance testing demonstrated that the differences in the design and performance of the subject device do not affect the intended use of the device or raise any new questions on safety and effectiveness of the ICS Dizcovery.

In conclusion, ICS Dizcovery is substantially equivalent to the predicate device ICS Impulse with respect to Intended Use, technological characteristics, and non-clinical Performance data.

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation was conducted according to ISO 10993-1:2018. The following tests were considered applicable:

- Cytotoxicity
- Sensitization
- Irritation

The device and its accessories are classified as limited contact (≤24 hours) contact and contact with Intact skin. No issues were found during biocompatibility testing.

Electrical safety, EMC, and other applied standards

The ICS Dizcovery system was tested to and complies with the following applicable safety, electromagnetic compatibility standards and all other applicable standards:

- IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Edition 3.2), Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+AMD1:2020 (Edition 4.1), General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-4-2 Ed. 1.0 (2016), Medical Electrical Equipment – Part 4-2: Guidance and Interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60601-1-6:2010+A1:2013+A2:2020 (Edition 3.2), Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability,
- IEC 62366-1:2015+ AMD1:2020 (Ed.1.1), Medical devices - Application of usability engineering to medical devices.
- IEC 62304:2006 + A1:2015, Medical Device Software – Software Lifecycle processes
- IEC 60825-1:2014+ISH1:2017+ISH2:2017 (Edition 3.0), Safety of laser products - Part 1: Equipment classification and requirements
- IEC 62471:2006, Photobiological safety of lamps and lamp systems
- ANSI S3.45-2009 (Reaffirmed 2019)- American National Standard Procedures for Testing Basic Vestibular Function

Software Verification and Validation Testing

Software Verification and Validation testing were conducted, and Basic Documentation Level was provided as recommended by FDA's Guidance for Industry and Staff 'Content of Premarket Submissions for Device Software Functions'.

Mechanical testing

The ICS Dizcovery successfully underwent mechanical testing to ensure that the performance of the device is not degraded by wear and tear over its useful lifetime. A summary of the conducted testing is provided below:

- ICS Dizcovery goggle stimuli projection system cycling accuracy test
- Scratch resistance durability testing of the ICS Dizcovery goggle mirror
- ICS Dizcovery goggle head strap pull cycle durability test
- ICS Dizcovery goggle USB cable bend and pull cycle durability testing

CONCLUSION

The nonclinical performance data support the safety of the device. The hardware and software verification and validation activities demonstrate that the ICS Dizcovery performs as intended in the specified use conditions. The results of these activities demonstrate that the ICS Dizcovery is as safe & effective as the predicate device, rendering it substantially equivalent.