DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 23, 2015

Otodynamics, Ltd.
% Mr. Christopher Sloan
Principal Consultant
Quintiles Consulting
1801 Rockville Pike, Suite 300
Rockville, MD 20852

Re: K143395
Trade/Device Name: Otodynamics Otoport/Otocheck OAE+ABR Device Family
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked response auditory stimulator
Regulatory Class: Class II
Product Code: GWJ, EWO
Dated: November 25, 2014
Received: November 26, 2014

Dear Mr. Sloan,

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,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143395

Device Name
Otoport/Otocheck OAE+ABR

Indications for Use *(Describe)*

The Otodynamics Otoport/Otocheck OAE+ABR device is indicated for use when there is a requirement to screen for hearing disorders by objective and non-invasive means. ABR, TEOAE and DPOAE screening test results are automatically interpreted and a clear 'Pass' or 'Refer' result is presented to the user who will be a trained screener, audiologist or medical professional. Use of the device is indicated when the patient is unable to give reliable voluntary responses to sound, especially with infants. Use of the device facilitates the early detection of hearing loss and its characterization.

The TEOAE and DPOAE analytical functions of the device are indicated when objective non-invasive clinical investigations require the characterization and monitoring of the functional status of the peripheral auditory function. For this purpose the device is intended to be used by audiologists or other audiologically skilled professionals. These TEOAE and DPOAE tests are applicable to populations of any age to obtain objective evidence of peripheral auditory function.

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.

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510(K) SUMMARY

Otodynamics Otoport/Otocheck OAE+ABR Family

510(k) Owner

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Date Prepared: November 5, 2014

Device Tradenames: Otodynamics Otoport/Otocheck OAE+ABR Device Family, consisting of:

- Otoport OAE+ABR Advance
- Otoport OAE+ABR DP+TE
- Otoport OAE+ABR Screener

- Otocheck OAE+ABR
- Otocheck OAE+ABR LE
- Otocheck ABR Screener
- Otodynamics ABR Upgrade Kit

Device Common or Usual Name:

Otoacoustic emission analyser and auditory evoked response stimulator

Classification Name:

Audiometer [class II, 21 CFR Section 874.1050; product code EWO; Panel 77 (Ear, Nose & Throat)]

Evoked response auditory stimulator [class II, 21 CFR Section 882.1900; product code GWJ; Panel 84 (Neurology)]

Predicate Devices:

Otodynamics Otoport (K072033) for otoacoustic emission functions

GSI Audioscreener (K024205) and GN Otometrics Madsen AccuScreen Type 1077 (K132957) for auditory brainstem functions

Device Description:

The Otodynamics Otoport/Otocheck OAE+ABR device is a compact, handheld, battery-powered electronic device which records physiological responses to sound for the purpose of hearing testing. The device records two responses of the auditory system to sound, namely the otoacoustic emission (OAE) response from the inner ear and the auditory brainstem response (ABR) from the brain. The OAE response is acoustically stimulated and recorded via an insert earphone device called a 'probe'. The ABR response is also acoustically stimulated via the OAE probe but is recorded electrically via self-adhesive conducting pads called 'electrodes', which are placed on the scalp.

The device provides-

- A hearing screening function based on the detection of either OAE or ABR responses
- An analysis of OAE responses for use in the clinical investigation of hearing disorders.

For hearing screening purposes the responses are automatically analyzed and interpreted to give an unambiguous Pass / Refer result. A 'Pass' result means that normally expected responses to the primary speech frequency sounds have been positively identified and no further audiological investigation is indicated. A 'Refer' result means that normally expected responses have not been identified indicating further audiological investigation unless a poor test environment is indicated in which case a retest under better conditions is recommended.

The Otoport/Otocheck OAE+ABR provides identical OAE analyses to the predicate Otoport OAE device, which is incorporated in the new device. The ABR screening function of the new device uses the same conventional ABR technologies used by the predicate devices. Tests have demonstrated the device to perform well in the clinical environment and to deliver high sensitivity and specificity as a screener.

Intended Use / Indications for Use

The Otodynamics Otoport or Otocheck OAE+ABR has the same fundamental intended use as the three predicate devices namely use in screening for hearing-related disorders. The indications for use of the two predicate devices which include both OAE and ABR screening methodologies are comparable to that of the Otodynamics Otoport/Otocheck OAE+ABR. The differences that exist in the detailed implementation of these methodologies do not alter efficacy or efficiency of the Otodynamics Otoport/Otocheck OAE+ABR device for screening. Therefore, the Otodynamics Otoport/Otocheck OAE+ABR has the same intended use as the predicate devices.

The Otodynamics Otoport/Otocheck OAE+ABR device is indicated for use:

> "when there is a requirement to screen for hearing disorders by objective and non-invasive means. ABR, TEOAE and DPOAE screening test results are automatically interpreted and a clear 'Pass' or 'Refer' result is presented to the user who will be a trained screener, audiologist or medical professional. Use of the device is indicated when the patient is unable to give reliable voluntary responses to sound, especially with infants. Use of the device facilitates the early detection of hearing loss and its characterization.
>
> The TEOAE and DPOAE analytical functions of the device are indicated when objective non-invasive clinical investigations require the characterization and monitoring of the functional status of the peripheral auditory function. For this purpose the device is intended to be used by audiologists or other audiologically skilled professionals. These TEOAE and DPOAE tests are applicable to populations of any age to obtain objective evidence of peripheral auditory function."

Technological Characteristics

The Otoport/Otocheck OAE+ABR has the identical otoacoustic emission (OAE) based functions compared to the Otodynamics' Otoport device [K072033]. The Otoport/Otocheck OAE+ABR device only differs from Otodynamics' Otoport device [K072033] by the inclusion of an auditory brainstem response (ABR) screening function comparable to that included in the Audioscreener [K024205] and the GN Otometrics AccuScreen [K132957] devices. Otoport/Otocheck OAE+ABR is also comparable to the Audioscreener and the AccuScreen with respect to the combination of OAE and ABR screening functions in one instrument.

Any differences in technological characteristics (e.g., design, materials) between the Otoport/Otocheck OAE+ABR and the predicate devices do not raise new types of safety or effectiveness questions. In addition, accepted scientific methods exist for assessing the effect of these new characteristics, and have been applied.

Performance

The Otoport/Otocheck OAE+ABR meets the requirements of a hearing screener met by the predicate devices viz. in that it is efficient in the detection of normal healthy ABR and OAE responses (i.e., high specificity), and reliable in its ability to detect the absence of ABR and OAE (i.e., high sensitivity). Based on the results of the bench testing validated by clinical evaluations, the Otoport/Otocheck OAE+ABR is adequately designed for its intended use and this supports a determination of substantial equivalence.

Conclusion

The Otoport/Otocheck OAE+ABR has the same intended use and comparable technological characteristics as the predicates. Any differences in technological characteristics between the Otoport/Otocheck OAE+ABR and the predicates do not raise new types of safety or effectiveness questions. In addition, accepted scientific methods exist for assessing the effect of these new characteristics. Bench performance testing and testing in the clinical environment demonstrate that the functionality, integrity, and safety of the Otoport/Otocheck OAE+ABR are adequate for its intended use and support a determination of substantial equivalence to marketed devices.