DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 2, 2017

dB Diagnostic Systems, Inc.
% Robyn Kressin
Associate Regulatory Consultant
MEDIcept, Inc.
200 Homer Avenue
Ashland, MA 01721

Re: K171038
Trade/Device Name: Hearing Healthcare Pro
Regulation Number: 21 CFR 874.1090
Regulation Name: Auditory Impedance Tester
Regulatory Class: Class II
Product Code: ETY
Dated: June 30, 2017
Received: July 3, 2017

Dear Robyn Kressin:

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,

Eric A. Mann -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)*
K171038

Device Name
The Hearing Healthcare Pro

Indications for Use *(Describe)*
The Hearing Healthcare Pro software will capture audiometry test results, and will allow user input of tympanometry results, physical examination results, and patient history. The software will summarize the inputted data and provide a "normal" or "abnormal" determination. If the decision is "abnormal", the software will make a recommendation for clinical follow-up. The dB Diagnostic Systems, Inc. software is for adult use only and is intended to be used by healthcare providers not normally trained or experienced in hearing, audiology, or otology, such as primary care providers.
The Hearing Healthcare Pro software is not intended to make a clinical diagnosis.

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

for the dB Diagnostic Systems, Inc.
Hearing Healthcare Pro
(per 21CFR 807.92)
K171038

1. SUBMITTER/510(K) HOLDER

dB Diagnostic Systems, Inc.

Official Contact: Dr. Steven Levine
Telephone: 203-984-0240

Consultant: Robyn Kressin
MEDIcept, Inc.
200 Homer Ave
Ashland, MA 01721

Date Prepared: April 5, 2017

2. DEVICE NAME

Proprietary Name:	Hearing Healthcare Pro
Common/Usual Name:	Hearing Healthcare Pro
Classification Name:	Tester, Auditory Impedance
Regulation Number:	21 CFR 874.1090
Product Code:	ETY
Classification Panel:	Ear Nose & Throat
Device Classification:	II

3. PREDICATE DEVICE

K133012 - Sentiero manufactured by PATH Medical GmbH

4. DEVICE DESCRIPTION

The Hearing Healthcare (HHC) Pro is software designed to be used by healthcare providers (HCP) not normally trained or experienced in hearing, audiology, or

otology, such as primary care providers. The HHC Pro software is not intended to make a clinical diagnosis. The HHC Pro software is a screening product. The software aggregates the inputted data and determines whether the person's hearing is considered normal or abnormal. If the results are abnormal, the software provides a recommendation for further clinical consultation with a licensed physician with expertise in Ear, Nose and Throat (ENT).

The HHC Pro software compiles the hearing information previously available to physicians, classifies the data as normal or abnormal with respect to any measureable hearing loss, and identifies the presence of asymmetric hearing results. The health care provider uses the HHC Pro to enter hand-held tympanometry results, limited clinical history, and limited physical examination findings, including a Rinne tuning fork test at 512Hz, to further identify patients who would benefit from an ENT evaluation.

The HHC Pro device comprises the HHC Pro Software. With the HHC Pro Software, dB Diagnostic Systems distributes the Auditdata/Otovation Amplitude T4 audiometer manufactured by Auditdata A/S, a 512Hz Rinne tuning fork, and the Microsoft Surface Pro 4 tablet preloaded with the Microsoft Windows 10 operating system and the HHC Pro Software. An Amplivox Otowave 102 Tympanometer may also be distributed with the HHC Pro software.

The Auditdata (registered establishment 3008386587) Otovation Amplitude T4 is a Class II exempt product in Sec. 874.1050 Audiometer under product code EWO.

5. INTENDED USE / INDICATIONS FOR USE

The Hearing Healthcare Pro software will capture audiometry test results, and will allow user input of tympanometry results, physical examination results, and patient history. The software will summarize the inputted data and provide a "normal" or "abnormal" determination. If the decision is "abnormal", the software will make a recommendation for clinical follow-up. The dB Diagnostic Systems, Inc. software is for adult use only and is intended to be used by healthcare providers not normally trained or experienced in hearing, audiology, or otology, such as primary care providers.

The Hearing Healthcare Pro software is not intended to make a clinical diagnosis.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The HHC Pro device is similar to the Sentiero predicate device (K133012) in that both devices include software intended to compile hearing screening information. The software in both systems collects information from portable hearing testing equipment and provides output based on the information provided. Both devices are classified under FDA product code of ETY, Tester, Auditory Impedance.

The HHC Pro is different from the Sentiero predicate device in that the HHC Pro device captures audiometry results from a third-party pure tone audiometer and allows health care professionals (HCPs) to record patient history, otoscopic examination, and tympanometry results. It provides recommendations for HCPs; while the Sentiero predicate device performs hearing screening or diagnostic testing and other diagnostic tests, whose results are interpreted directly by hearing specialists.

Additionally, the predicate device contains an audiometer and software as one device. In contrast, the HHC Pro device is comprised only of software, an audiometer is sold with the device.

The Hearing Healthcare Pro is substantially equivalent to the predicate device, as it has similar indications for use, operational characteristics, and fundamental technological characteristics as the Sentiero.

7. PERFORMANCE TESTING

The dB Diagnostic Systems, Inc. HHC Pro has been designed and manufactured in

compliance with the company's performance specifications and the following FDA recognized consensus standards, voluntary industry standards, and FDA guidance documents:

- AAMI / ANSI / ISO 15223-1: 2012, Medical devices - symbols to be used with medical devices labels, labeling, and information to be supplied - part 1: general requirements. (General I (QS/RM))
- ISO 14971:2007, Medical devices - Application of risk management to medical devices
- ANSI S3.1-1999 (R2008) American National Standard Maximum Permissible Ambient Noise Levels for Audiometric Test Rooms
- FDA Guidance Document, General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 11. 2002
- FDA Guidance Document, Guidance for the content of Premarket Submission for Software in Medical Devices, May 11, 2005

The HHC Pro has been tested and is in compliance with internal software validation bench testing to compare the HHC Pro input test results to the gold standard, Board-Certified Otolaryngologist reviewers for equivalence in the output responses. In addition to the software validation bench testing performed, software verification was also conducted to FDA regulations, standards and guidance document requirements. The results of this testing conclude the software has met the design requirements.

8. CONCLUSION

The Hearing Healthcare Pro does not raise new issues of safety or effectiveness and is substantially equivalent to the predicate device.