DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 16, 2016

Maico Diagnostics Gmbh
Mr. Uwe Ledworuski
Regulatory Affairs Manager
Sickingenstr. 70-71
Berlin, 10553 DE

Re: K162210
Trade/Device Name: Touchtymp
Regulation Number: 21 CFR 874.1090
Regulation Name: Auditory Impedance Tester
Regulatory Class: Class II
Product Code: ETY
Dated: August 2, 2016
Received: August 5, 2016

Dear Mr. Ledworuski:

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

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)*
K162210

Device Name
touchTymp

Indications for Use *(Describe)*
The touchTymp tympanometer is an electroacoustic test instrument that produces controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. It features tympanometry and acoustic reflex audiometry.

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.

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510(K) SUMMARY

touchTymp

Submitter Information:

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Contact Person	Uwe Ledworuski, Manager Regulatory Affairs
Date Summary Prepared	June 11, 2016

Device Identification:

Trade Name	touchTymp
Common Name	Audiometric equipment
Classification Name	Tester, Auditory Impedance
Product Code	ETY
Panel	Ear Nose & Throat
Device Class	Class II (According to 21 CFR 874.1090)
510(k) No.	K162210

Predicate Devices:

Trade Name	MI 24
Manufacturer	MAICO Hearing Instruments, Inc.
510(k) No.	K905704
Date Cleared	04/30/1991

Device Description	The touchTymp is an auditory impedance analyser. The device is intended to change the air pressure in the external auditory canal and measure and graph the mobility characteristics of the tympanic membrane to evaluate the functional condition of the middle ear. The device is used to determine abnormalities in the mobility of the tympanic membrane due to stiffness, flaccidity, or the presence of middle ear pathologies. The device is also used to measure the acoustic reflex threshold which occurs due to contractions of the stapedial muscle following exposure to a strong stimulus. This test allow to assess between central and peripheral pathologies and to identify where the patients uncomfortable loudness level may reside. The instrument is software controlled. The software controls the probe (tone and pressure) stimuli, measures the result and presents the result on a built in display. All functions are set and interpreted by the operator. The technological characteristics are substantially equivalent with predicate device. All technological characteristics are in compliance with the consensus standard ANSI S3.39 for auditory impedance testers.
Indications for Use	The touchTymp tympanometer is an electroacoustic test instrument that produces controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. It features tympanometry and acoustic reflex audiometry.
Intended operator	The touchTymp tympanometer is intended to be used by audiologists, ENTs, hearing healthcare professionals, or other trained technicians.
Technological Characteristics	The instrument is software controlled. The software controls the probe (tone and pressure) stimuli, measures the result and presents the result on a built in display. All functions are set and interpreted by the operator. The technological characteristics are substantially equivalent with predicate device. All technological characteristics are in compliance with the consensus standard ANSI S3.39 for auditory impedance testers.
Nonclinical tests summary	Following the design control procedure the design verification and validation were performed according to current standards for medical device safety and EMC and performance of impedance tester. The device was found in compliance with current standards

	and demonstrated substantial equivalence with the predicate device.
Clinical tests	None applicable
Conclusion	The touchTymp as a modification to the predicate device (the previous cleared revision of MI 24 uses similar technology and has the same intended use as the predicate device. The verification and validation activities show substantial equivalence with the predicate device and that the modified touchTymp is as safe and effective as the predicate device for its claimed purpose.