DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 29, 2017

Maico Diagnostics GmbH
Amy Yanta
Director of Regulatory Affairs
Sickingenstr. 70-71
Berlin, 10553 DE

Re: K171506
Trade/Device Name: Easyscreen
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO, GWJ
Dated: Undated
Received: July 27, 2017

Dear Amy Yanta:

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)*
K171506

Device Name
Easyscreen

Indications for Use *(Describe)*
The device DPOAE and TEOAE modules are intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions or Transient Otoacoustic Emissions technology. The target population for the modules includes all ages.

The device ABR module is intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the inner ear, the auditory nerve and the brainstem. The target population for the ABR module is newborns and infants up to 6 months of age.

The easyScreen is intended to be used by audiologists, ENTs, hearing healthcare professionals, or other trained technicians in a hospital, clinic, healthcare facility or other suitable quiet environment as defined in standard ISO 8253-1.

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

I. Administrative Information

Submitter: MAICO GmbH
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Date Summary Prepared: May 10, 2017

II. Device Identification

Trade Name: easyScreen

Common Name: otoacoustic emission device/evoked response auditory stimulator and measurements
Device Classification Name: Audiometer/Stimulator, Auditory, Evoked Response

Panel: Ear Nose & Throat / Neurology (874.1050/882.1900)

Device regulatory classification: Class II

Product Code: EWO/GWJ

Predicate Device 1: Titan (with DPOAE440 and ABRIS440), cleared on 05/05/2011 via K103760

Predicate Device 2: Titan (with TEOAE440), cleared on 06/20/2013 via K130795

III. Device Description

The device is audiometric equipment used for testing of inner ear and auditory brainstem abnormalities.

easyScreen features a touch-screen display and user-friendly software in a compact hardware design. easyScreen can be purchased with various licenses allowing you to perform different hearing screening tests.

easyScreen uses auditory brainstem response (ABR) technology to screen patients for hearing loss. A modified click stimulus, the CE-Chirp®, of 35 dB nHL is delivered into the patient's ear while electrodes placed on the patient's head measure EEG activity.

The EEG is processed and analyzed automatically using the easyScreen's response detection algorithm. When a response is detected, the screening is stopped automatically and a Pass

result is assigned to the test ear. When no response is detected after 3 minutes of EEG activity has been processed, a Refer result is assigned.

Auditory brainstem response (ABR) test produces a short acoustic stimulus and measures via transcutaneous electrodes the auditory evoked potentials from the inner ear, the auditory nerve and the brainstem.

Distortion product otoacoustic emissions (DPOAE) technology uses pairs of pure tones presented in sequence to screen patients for cochlear hearing loss. Responses to the stimulus are predictable and therefore can be measured via a sensitive microphone placed in the patient's ear canal.

Transient otoacoustic emissions (TEOAE) technology uses a click stimulus to screen patients for cochlear hearing loss. Responses to the stimulus are predictable and therefore can be measured via a sensitive microphone placed in the patient's ear canal. The response can be divided into frequency bands for assessment.

IV. Indications for Use

The device DPOAE and TEOAE modules are intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions or Transient Otoacoustic Emissions technology. The target population for the modules includes all ages.

The device ABR module is intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the inner ear, the auditory nerve and the brainstem. The target population for the ABR module is newborns and infants up to 6 months of age.

The easyScreen is intended to be used by audiologists, ENTs, hearing healthcare professionals, or other trained technicians in a hospital, clinic, healthcare facility or other suitable quiet environment as defined in standard ISO 8253-1.

V. Technological Characteristics

The easyScreen consists of a handheld unit that utilizes a touchscreen display and a rechargeable battery. A simple cradle is included to support charging of the device's battery. The device supports

Bluetoothcommunication with a label printer for the purpose of printing screening results.

A comparison between the new and predicate devices shows that the technological characteristics and indications for use are equivalent. The device employs similar technology to accomplish the same tasks as the predicates. A detailed table is provided below.

Equivalence

Predicate Chart 1:

Description	Titan with TEOAE440 (k130795)	easyScreen
Type	Audiometer	Same
Regulation Number	21 CFR 874.1050 (otoacoustic emission device)	Same
Classification Product Code	EWO	Same

Regulatory Class	Class II	Same
Indications for Use	The Titan with TEOAE440 is intended for use in the audiologic evaluation and documentation of ear disorders using Transient Evoked Otoacoustic Emissions. The target population for Titan with TEOAE440 includes all ages.	The device DPOAE and TEOAE modules are intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions or Transient Otoacoustic Emissions technology. The target population for the modules includes all ages. The device ABR module is intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the inner ear, the auditory nerve and the brainstem. The target population for the ABR module is newborns and infants up to 6 months of age.
Target Population	The devices are suitable for all populations including new-born infants	Same
Intended User	The Titan System is to be used by trained personnel only such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of education.	Same (or trained user with supervision of a professional)
TEOAE Stimulus		
Frequency Range	500 to 5500Hz	same
Stimuli Type	Non-Linear and Linear Short duration signal (Click) According to IEC 60645-3	same
Level	30 to 90 dB peSPL	same
Level Step	1 dB SPL	same
Transducer	Dedicated OAE Probe	same
Probe Detection	Auto detection	same
Recording		
A/D Resolution	24 bit	same
Artifact Reject System	0 -> +60 dB SPL or off	same
Automatic test with display of PASS-REFER	Yes	same

Equivalence Predicate Chart 2:

Description	Titan (k103760)		easyScreen
	With ABRIS440	With DPOAE440	
Type	Auditory Brainstem Response – Audiometric equipment	Audiometer	Same
Regulation Number	21 CFR 882.1900 (Evoked response auditory stimulator)	21 CFR 874.1050 (otoacoustic emission device)	Same
Classification Product Code	GWJ	EWO	Same
Regulatory Class	Class II	Class II	Same
Indications for Use	The Titan with ABRIS440 is intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the inner ear, the auditory nerve and the brainstem.	The Titan with DPOAE440 is intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions.	The device DPOAE and TEOAE modules are intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions or Transient Otoacoustic Emissions technology. The target population for the modules includes all ages. The device ABR module is intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the inner ear, the auditory nerve and the brainstem. The target population for the ABR module is newborns and infants up to 6 months of age.

Target Population	Children and newborn	The patient group includes all ages and sexes.	Same
Anatomical Sites	Examination of Ear and hearing nerves	Examination of Ear	Same
Safety Standards	IEC 60601-1	IEC 60601-1	Same
Performance standard	IEC 60645-7	IEC 60645-6	Same
Device Type	Screening device	Screening and diagnostic	Same (PASS/REFER)
	(PASS/REFER) result		
System Configuration	1 -channel ABR system operated through a handheld base unit. The base unit can be operated stand alone or PC controlled through USB or Bluetooth.	[redacted]	1 -channel ABR system operated through a handheld base unit. The base unit is operated as a stand alone device
Display Information	PASS/REFER status, indicated with value between 0 and 100% where 100% indicates a pass. EEG peak or RMS value, rejection status, residual noise and what transducer(s) are detected.		Noise status, detected transducer, artifact %, PASS/REFER status
Stimulus	Click and Chirps	2 pure tones	same
Electrode quality check	YES	[redacted]	same
Impedance Test	Before recording: Electrode impedance is measured if they are above 10kOhm, below 10 kOhm or below 3 kOhm.		Similar impedance test; acceptable impedance <40kOhm.
Binaural screening	YES		same
Pre-amplifier channels	1		same
Stimulus rate	90/s		same
Pre-amplifier Gain	64 dB (fixed) + 64dB (Variable)		same
Stimulus Level	30,40 and 45dB HL	30 dB SPL to 80 dB SPL	same
Masking	None	[redacted]	same
Transducers	Titan Probe (mono) Stereo headset: TDH39 and EAR3A		OAE probe, RadioEar IP30 insert earphone
Frequency range (f2)	[redacted]	500Hz – 10kHz	same

VI. Summary of Non-Clinical Testing

Design verification and validation were performed according to current standards for OAE and ABR to assure the device meets its performance specifications. EMC and Safety was performed in compliance with recognized standards IEC 60601-1 series, Medical Electrical Equipment – General requirements for basic safety and essential performance. The product meets the requirements from the international standard for OAE measurements IEC 60645 series. Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in medical Devices." The software for this device was considered as a "moderate" level of concern since a malfunction of, or a latent design flaw in, the Software Device could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury. No clinical tests were performed, but based on the fulfillment of the international standards for OAE and ABR we believe the device is safe and effective. The auditory impedance testing characteristics and safety systems were compared and found to be comparable.

VII. Summary of Clinical Testing

Not applicable. Not required to establish substantial equivalence.

VIII. Conclusion

We have compared the intended use and performance characteristics with the predicate devices. The easyScreen was tested according to current standards and the differences found between the devices were related to functionality, not in relation to safety and efficiency. The easyScreen conforms to the current standards. After analyzing bench testing, safety, EMC, and software validation (with risk analysis) testing we conclude that the easyScreen is found to be substantially equivalent to the predicate devices in technological characteristics and indications for use.