Promaxo, Inc.
℅ Eva Hellman
RA/QA Manager
70 Washington St, Suite 407
OAKLAND CA 94607

March 3, 2021

Re: K202518
Trade/Device Name: Promaxo MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, MOS
Dated: January 21, 2021
Received: January 22, 2021

Dear Eva Hellman:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202518

Device Name
Promaxo MRI System

Indications for Use *(Describe)*
The Promaxo Magnetic Resonance Imaging (MRI) System is an office-based MRI system for producing images that display the prostate and adjoining tissues. When used by a trained urologist or interventional/urologic radiologist, the system is intended to be used for targeting prostatic lesions under MR guidance in alignment with the current standard of care. Promaxo MR images are not intended to be used for diagnostic purposes, and a 3T MR image acquired without an endorectal coil is a required input for guidance using the Promaxo MRI System.

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

K202518

Submitter:	Promaxo, Inc. 70 Washington St., Suite 407, Oakland, CA 94607 510-770-6819
Contact Person:	Eva Hellman RA/QA Manager (510) 770-6961 ehellman@promaxo.com
Date:	8/31/2020
Trade or Proprietary Name:	Promaxo MRI System
Common or Usual Name:	System, Nuclear Magnetic Resonance Imaging
Classification Name:	Magnetic Resonance Diagnostic Device
Product Code:	LNH, MOS
Regulation Number:	892.1000
Classification:	Class II

Predicate Device:

Trade Name	Common Name	Class	Product Code	Manufacturer	K-number
ASM-030PIII (OPENMARK 111), ASM-040P (OPENMARK 4000), ASM-050P (OPENMARK 5000)	MRI Systems	II	LNH	Shenzhen Anke High-Tech Co. Ltd.	K113281

Indications for Use

The Promaxo Magnetic Resonance Imaging (MRI) System is an office-based MRI system for producing images that display the prostate and adjoining tissues. When used by a trained urologist or interventional/urologic radiologist, the system is intended to be used for targeting prostatic lesions under MR guidance in alignment with the current standard of care. Promaxo MR images are not intended to be used for diagnostic purposes, and a 3T MR image acquired without an endorectal coil is a required input for guidance using the Promaxo MRI System.

Description of the Device and Summary of the Technological Characteristics

Promaxo's MRI system is an open configuration MRI system composed of an array of permanent magnets arranged to provide a constant in-plane magnetic field strength and a built-in z-gradient within its field of view. The system utilizes electromagnetic gradient coils, RF coils, and other components such as the spectrometer and signal amplifiers to capture, reconstruct and display magnetic resonance images of objects within its field of view. Promaxo MRI System's technological features are substantially equivalent to its predicate device. Both of them:

- Are comprised of a magnet, magnet enclosure, electromagnetic gradient coils, RF transmission coil, and RF receiver coil
- Have the main magnet comprised of an array of permanent magnets
- Measure spatial distribution of protons exhibiting magnetic resonance
- Are capable of imaging T1, T2, and Diffusion-Weighted Imaging
- Are cryogen free
- Provide an interactive user interface to operate the device

Promaxo's MRI system differs in technology in the following ways:

- The z-gradient is built into the main magnetic field and, as a result, the system does not require an electromagnetic z-gradient coil
- The device includes a template holder to be used for procedures under MR guidance
- The device includes an MR guidance user interface workflow such as template calibration and registration with imported MR images

A detailed comparison of the Promaxo MRI System and predicate device is described below:

Product	Promaxo MRI System	OPENMARK III, OPENMARK 4000 and OPENMARK 5000
Regulatory Information		
Manufacturer	Promaxo	Shenzhen Anke High-tech Co., Ltd
510(k) Number	K202518	K113281
Product Code	LNH, MOS	LNH
Regulation No.	892.1000	892.1000
Intended Use	The Promaxo Magnetic Resonance Imaging (MRI) System is an office-based MRI system for producing images that display the prostate and adjoining tissues. When used by a trained urologist or interventional/urologic radiologist, the system is intended to be used for targeting prostatic lesions under MR guidance in alignment with the current standard of care. Promaxo MR images are not intended to be used for diagnostic purposes, and a 3T MR image acquired without an endorectal coil is a required input for guidance using the Promaxo MRI System.	MRI SYSTEMS, including ASM-030Pl1 (OPENMARK 1ll), ASM-040P (OPENMARK 4000) and ASM-050P (OPENMARK 5000). Are indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross-sectional images, and that display the internal structure and/or function of the head, body, or extremities. These images when interpreted by a trained physician yield information that may assist in diagnosis.
Magnet		
Type of Magnet	Permanent Magnet	Permanent Magnet
Magnetic field strength in FOV	0.058T-0.074T	0.3T, 0.4T, 0.5T
Patient accessible bore-space	Open configuration	Open configuration
Type of installation	Fixed	Fixed
Shimming	Passive	Passive
Gradient System		
Cooling System	Cryogen free	Cryogen free
Gradient System Description	Two-axis electromagnetic coils for x- and y-gradients, built-in permanent z-gradient	Three-axis electromagnetic coils
dB/dt (time rate of change of magnetic field)	Always within normal operating mode, under normal use conditions	Always less than 20T/s, under normal using condition

Product	Promaxo MRI System	OPENMARK III, OPENMARK 4000 and OPENMARK 5000
Radiofrequency System		
RF Transmission Coil	Peak Power: 4 kW Center Frequency: 2.77 MHz Transmission Bandwidth: 2.47 to 3.07 MHz Configuration: Integrated	Peak Power: 6 kW Center Frequency: 21.29 MHz Transmission Bandwidth: Unknown Configuration: Integrated
RF Receive Coils	Patient wearable receive coil (plug-in type)	Patient wearable receive coil (various configurations, plug-in type)
SAR (Specific Absorption Rate) Management	No active SAR management required	No active SAR management required
Operation		
Mains Power Requirements	Power Supply: 208V, 3 phase Power Frequency: 60 Hz Input Power: 15 kVA	Power Supply: 380V 3N~ Power Frequency: 50 Hz Input Power: 15 kVA
Control System	Spectrometer	Spectrometer
Image Acquisition and Processing		
Image Resolution	Varies	Varies
Slice Thickness	Selectable by technician	Selectable by technician
Pulse Sequences	T1, T2, DWI	T1, T2, DWI, DCE
Imaging Protocols	T1, T2, DWI of prostate and adjoining tissues Patient wearable receive coil	T1, T2, DWI of head, body and extremities Patient wearable receive coil Exogeneous contrast media may be applied.
Image Processing	None	None
DICOM Compliance	Yes	Yes
Graphical User Interface	Touchscreen keyboard/mouse	Display, keyboard/mouse
Other		
Software Applications	User operates the system using a main user interface application	User operates the system using a main user interface application
Networking	Network interface for archival and retrieval	Network interface for archival and retrieval

Summary of Non-Clinical Testing

Promaxo MRI System has been evaluated to demonstrate substantial equivalence related to medical electrical equipment, risk management, hardware and software verification and validation, and image quality and has been found to conform to the following medical device standards:

- IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-33:2010, AMD1:2013, AMD2:2015, Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
- NEMA MS 2-2008 (R2014), Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images.
- NEMA MS 4-2010, Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices
- NEMA MS 5-2018, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging.
- NEMA MS 6-2008 (R2014), Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging
- NEMA MS 8-2016, Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems
- NEMA MS 9-2008 (R2014), Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images
- NEMA MS 10-2010, Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging Systems
- NEMA MS 14-2019 Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems
- ISO 10993-1:2018, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

Navigation accuracy testing on phantoms was performed to support the indications for use and substantial equivalence. The test included users performing template localization and needle localization activities using the Promaxo MRI System.

Summary of Clinical Testing

Sample clinical images and testing on sample clinical images were provided to support substantial equivalence. Users performed registration accuracy and motion studies using the Promaxo MRI System on clinical images of human subjects.

An end-to-end clinical feasibility study was conducted.

Conclusion

The testing demonstrates that the Promaxo MRI System is as safe and effective as the predicate for the intended use of surgical localization of previously diagnosed prostate lesions on a diagnostic 3T MRI. The subject device is substantially equivalent to the legally marketed predicate device and conforms to applicable medical device safety and performance standards.