September 5, 2023

Promaxo, Inc.
% Veronica Sanz
QA/RA Manager
70 Washington St, Suite 407
Oakland, CA 94607

Re: K232361
Trade/Device Name: Promaxo MRI System II
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, MOS
Dated: August 3, 2023
Received: August 7, 2023

Dear Veronica Sanz:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232361

Device Name

Promaxo MRI System II

Indications for Use *(Describe)*

The Promaxo Magnetic Resonance Imaging (MRI) System II 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 either a 1.5T or 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

Prepared on: 2023-08-04

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Promaxo, Inc.
Applicant Address	70 Washington St Suite 407 Oakland CA 94607 United States
Applicant Contact Telephone	(510) 462-5456
Applicant Contact	Ms. Veronica Sanz
Applicant Contact Email	vsanz@promaxo.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Promaxo MRI System II
Common Name	Magnetic resonance diagnostic device
Classification Name	System, Nuclear Magnetic Resonance Imaging
Regulation Number	892.1000
Product Code	LNH / MOS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K202518	Promaxo MRI System	LNH/MOS

Device Description Summary

21 CFR 807.92(a)(4)

The MRI System that is subject of this 510(k) is identical to the device cleared in K202518, with the exception of a modification to the Indications for Use statement.
The Promaxo 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Promaxo Magnetic Resonance Imaging (MRI) System II 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 either a 1.5T or 3T MR image acquired without an endorectal coil is a required input for guidance using the Promaxo MRI System.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The modified Indications for Use include co-registration with a diagnostic 1.5T MR image acquired without an endorectal coil.
This modification to the Indications for Use does not affect the safety and efficacy of the device because the device design and intended use are identical to the predicate.

Technological Comparison

21 CFR 807.92(a)(6)

The technological characteristics of Promaxo MRI System II are identical to the predicate device:
- 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
- Capable of imaging T1, T2, and Diffusion-Weighted Imaging
- Cryogen free
- Provide an interactive user interface to operate the device
- The z-gradient is built into the main magnetic field and, as a result, the system does notrequire 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

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-Clinical Testing
No design modifications have been made to the cleared Promaxo MRI System. The only change is to the Indications for Use. An assessment of the change was performed, and it was determined that the modified Indications for Use do not introduce any new risks. Thus, testing previously performed for the Promaxo MRI System is appropriate and sufficient for the modified Indications for Use. Therefore, no additional performance data is required.

Clinical Data
Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

Conclusions
Based on the technological characteristics, intended use and modified Indications for Use, the Promaxo MRI System II can be found substantially equivalent to the identified predicate device.