July 20, 2023

Insight Medbotics Inc.
% Mr. Joel Ironstone
President
Ironstone Product Development
Suite 108, 250 Carlaw Avenue
Toronto, Ontario M4M3L1
CANADA

Re: K223484
Trade/Device Name: IGAR System (1001.A)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: June 16, 2023
Received: June 22, 2023

Dear Mr. Ironstone:

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
Magnetic Resonance and Nuclear Medicine Team
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)*

K223484

Device Name

IGAR System (1001.A)

Indications for Use *(Describe)*

The IGAR System is intended to acquire magnetic resonance (MR) images of the breast anatomy and permits access to the breast for biopsy and localization procedures. A front breast restraint immobilizes the patient's breast to permit three-dimensional MR imaging to identify the location of the breast lesion(s) for the purposes of selecting a target for biopsy. The IGAR System guides a breast biopsy tool to the target location of the breast from which a biopsy can be obtained. The IGAR System is intended to be used by qualified professionals.

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.

K223484

510(k) SUMMARY

IGAR System (1001.A)

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Insight Medbotics Inc.
39 Charlton Ave
East Hamilton Canada
ON L8N 1Y3
Phone: 647-362-4684
Contact Person: Fazila Seker

Date Prepared: June 16, 2023

Name of Device

IGAR System (1001.A)

Device Classification and Product Code

Magnetic resonance diagnostic device, 21 CFR 892.1000, Class II, MOS

Predicate Devices

Vanguard Breast MRI System (K100113)-Primary Predicate
Affirm Prone Biopsy System (K153486)- Reference device

Indications for Use

The IGAR System is intended to acquire magnetic resonance (MR) images of the breast anatomy and permits access to the breast for biopsy and localization procedures. A front breast restraint immobilizes the patient's breast to permit three-dimensional MR imaging to identify the location of the breast lesion(s) for the purposes of selecting a target for biopsy. The IGAR System guides a breast biopsy tool to the target location of the breast from which a biopsy can be obtained. The IGAR System is intended to be used by qualified professionals.

Device Description

The IGAR System is a tool-positioning system for enabling accurate MR-guided breast biopsies. The IGAR System is designed to provide biopsy tool guidance and accurate targeting of lesions in the breast while the patient is in the MRI room– this creates the ability to "see and evaluate" within a single session.

The system consists of the following components:

- Workstation: Imports DICOM-formatted MR images from the MR scanner or a PACS server, from which the clinician can select its biopsy target and plan the needle path to this target.

- Patient Support: Positions the patient prone on the MR gantry, ready for the biopsy.
- Manipulator: The Manipulator positions tools for interaction with the patient to perform the biopsy; the Manipulator attaches to the IGAR Patient Support.
- Pendant: Allows the user to control tool movements.
- Control Cart: Provides signals and electrical power to the Manipulator, and coordinates information

The IGAR System integrates with an FDA-cleared MRI system from GE, 3 Tesla (3T) GE Discovery™ MR750 – 60cm (Bore size).

Clinical Testing

Clinical Data was not required for this submission.

Non-Clinical Testing

- ***Software Verification & Validation:***

  The IGAR System containing a moderate level of concern software was subjected to a design and development process including verification and validation.

  Software test results demonstrated 1) Software design outputs met the design input requirements and 2) software specifications conform to user needs and intended uses, and that requirements implemented through software can be consistently fulfilled.

- ***Functional Bench Testing***

  IGAR System functional bench testing included electronics, mechanical, packaging, and labelling verification activities. Functional testing included verification that when interfaced with the GE 3T MRI, the IGAR does not adversely affect MRI diagnostic image quality following NEMA (MS1, MS2, MS3) and ASTM (F2052, F2213, F2182) test methods. Verification test results demonstrate acceptance criteria were met, and design outputs met the design input requirements.

- ***Phantom Accuracy Testing***

  Verification of the IGAR System's end-to-end needle placement was performed in a representative clinical setting using a simulated tissue phantom and a 3T GE MRI. Predefined acceptance criteria for targeting accuracy were met.

  Test methods outlined in *IEC 60601-2-45 (Medical Electrical Equipment - Safety of Mammographic X-ray Equipment and Mammographic Stereotactic Devices)* were followed, with modifications for the MRI environment, to demonstrate the subject device meets its targeting accuracy specification.

- ***Biocompatibility***

Biocompatibility testing was conducted on patient contact materials according to ISO 10993-1

- ***Human Factors***

  Usability and human factors evaluation was performed per IEC 60601-1-6 (Medical Electrical Equipment – Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability) and FDA Guidance on Applying Human Factors and Usability Engineering to Medical Devices. The evaluation was successful in demonstrating the IGAR System is reasonably usable and can be used without use errors or problems that could result in serious harm.

- ***Reprocessing Validation and Shelf/Reuse-Life Verification***

  Manual cleaning, disinfection, and sterilization reprocessing methods were validated. Shelf and reuse life testing verified device performance was maintained after accelerated aging and simulated use testing.

- ***Standards Compliance***

- ASTM F2503-20 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
- ASTM F2052-21 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2182-19e2 Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance
- NEMA MS-1-2008 (R2020) Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging
- NEMA MS 2-2008 (R2020) Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- NEMA MS 3-2008 (R2020) Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes

- ISTA 3A 2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less
- ISO 11737-2 Third edition 2019-12 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

Non-clinical test results were analyzed to demonstrate substantially equivalent performance. All bench testing was performed under conditions that approximate the IGAR System's intended use: where necessary, simulated breast tissue phantoms were used; all testing requiring the MRI was conducted with a compatible 3T GE MRI.

All required bench testing activities have been completed for the IGAR System and it has been determined that it meets its functional and performance requirements. Results demonstrate that the IGAR system is substantially equivalent to the Vanguard Breast MRI System (K100113).

Comparison of Intended Use, Indications for Use and Technological Characteristics with the Predicate Device

Indications for Use Comparison:

Both the subject and predicate devices (Vanguard Breast, K100113) are intended to enable imaging and access to the breast for obtaining breast biopsies.

Both devices are indicated for use in female patients over the age of 18 with suspected or confirmed breast cancer requiring an MRI- guided breast biopsy for diagnosis and or staging. The intended users are Radiologists and MR Technologists trained in the conduct of MRI-guided biopsy procedures. Both devices are used in the MRI suite.

Therefore, IGAR System has the same intended use as the predicate device.

The indications for use of the IGAR System are a subset of the indications of use of the predicate device.

Both the predicate and subject devices are intended for MRI imaging of breast anatomy and permit access for biopsy and localization procedures. While the Vanguard Breast MRI System is indicated for both lesion localization and diagnostic imaging, the IGAR System is indicated for use in acquiring images only for lesion localization purposes. The IGAR system is not indicated to perform diagnostic imaging.

This subset of indications for use does not result in a new or different intended use than the predicate device and the intended use is therefore the same.

Technological Comparison:

The key difference between the subject and predicate device is that the IGAR system allows motorized percutaneous placement of devices for biopsy while the predicate biopsy guidance is performed manually based on a biopsy grid. Both systems enable the physician to position a biopsy device into the breast based on MR image guidance. Each system requires the user to determine the lesion location from MR image and determine the route by which the biopsy device reaches the location. The motorized nature of the IGAR System is similar to the Affirm Prone Biopsy System reference device (K153486).

All three systems, the subject, predicate, and reference devices, enable the physician to position a biopsy device into the breast based on image guidance. Each system requires the user to determine the lesion location and determine the route by which the biopsy device reaches the location.

Conclusion

The IGAR System has the same intended use, and differences in technological characteristics do not raise any questions of safety or efficacy. Performance demonstrates the equivalence and therefor the IGAR System is substantially equivalent to Vanguard Breast (K100113).