Harmonus Inc.
Nandini Murthy
Regulatory Consultant
110 Canal St
3rd Floor
Lowell, Massachusetts 01852

March 2, 2018

Re: K173312
Trade/Device Name: ProBx Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: January 16, 2018
Received: January 18, 2018

Dear Nandini Murthy:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

SECTION 4

INDICATIONS FOR USE STATEMENT

A completed Indications for Use Statement follows this page.

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)*
K173312

Device Name

ProBx Software

Indications for Use *(Describe)*

ProBx Software is intended for use as follows:
• ProBx Software is a computer-based image-guidance accessory intended for use in conjunction with commercially available Magnetic Resonance Imaging (MRI) systems and interventional devices.
• ProBx Software helps physicians guide biopsy instrumentation to targets that have been defined by the physician in MRI. The Software provides the clinician with image analysis and display of pre-procedural and intra-procedural MRI images of tracked accessory hardware and the target organs, along with the projected path to the target. The Software displays an MRI image of the current location of the interventional instrument for positioning confirmation.
• ProBx Software is intended to be used by physicians in a clinical setting for treatment planning and guidance for clinical, interventional, and/or diagnostic procedures of the prostate.

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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SECTION 5

510(k) SUMMARY

Submitter Name:	Harmonus, Inc.
Submitter Address:	110 Canal St. Lowell, MA 01852
Contact Person:	Nicole Mauro, CEO
Phone Number:	(617) 702-2271
Date Prepared:	10/18/2017
Device Trade Name:	ProBx Software
Device Common Name:	Image-guided, interventional planning software
Classification Name:	System, Image Processing, Radiological, LLZ
Classification regulation:	21 CFR 892.2050, Product Code LLZ
Predicate Device:	DynaCAD/Prostate Interventional, K133030

Device Description:

ProBx Software along with ProBx Hardware accessories is used for in-bore Magnetic Resonance Imaging (MRI) guided interventional and diagnostic procedures of the prostate. The ProBx Software is intended to be loaded onto a commercially available workstation and used as an accessory to commercially available MRI systems. The software receives pre-procedural and intra-procedural DICOM images and provides 2D and 3D visualization for treatment planning. The Software performs calculations on user-selected target locations to assist the clinician in manually utilizing the tracked accessory hardware to reach targets. The Software also provides MRI scan confirmation of positioning during the procedure.

Indications for Use:

ProBx Software is intended for use as follows:

- ProBx Software is a computer-based image-guidance accessory intended for use in conjunction with commercially available Magnetic Resonance Imaging (MRI) systems and interventional devices.
- ProBx Software helps physicians guide biopsy instrumentation to targets that have been defined by the physician in MRI. The Software provides the clinician with image analysis and display of pre-procedural and intra-procedural MRI images of tracked accessory hardware and the target organs, along with the projected path to the target. The Software displays an MRI image of the current location of the interventional instrument for positioning confirmation.

- ProBx Software is intended to be used by physicians in a clinical setting for treatment planning and guidance for clinical, interventional, and/or diagnostic procedures of the prostate.

Rationale for Substantial Equivalence:

	Submitted Device	Predicate Device #1	Reference Device #1
Proprietary/Trade Name	ProBx Software	DynaCAD/Prostate Interventional	SmartTarget
510(k) Number	n/a	K133030	K170250
Product Code	LLZ	LLZ	LLZ
Class	II	II	II
Target Anatomy	Prostate	Prostate	Prostate
Anatomy access	Transperineal	Transrectal	Transperineal
Modality	MR	MR	US fusion with MR, CT
Software			
Windows OS	Yes	Yes	Yes
Kiosk	Yes	Yes	Not known
Medical Imaging Software	Yes	Yes	Yes
Connectivity			
DICOM Import	Yes	Yes	Yes
Image Display			
General Image 2D/3D Review	Yes	Yes	Yes
Image Processing			
Registration: Fiducial-tracked Instrumentation in relation to patient anatomy	Yes	Yes	Yes
Required instrument registration and verification images prior to intervention	Yes	Yes	Yes
Planning and Navigation			
Interventional Hardware/Positioning Device	Yes (ProBx Grid with Calibrator and Patient Support)	Yes (DynaTrim Needle Guide and Patient Support)	Yes (3rd party Gridplate and Stepper)
Add Targets	Yes	Yes	Yes
Plan/Marks Location	Yes	Yes	Yes
MR-guided interventional planning with interventional hardware	Yes	Yes	Fusion with US
MR Placement verification	Yes	Yes	No, US

Table 5.1 Comparison of ProBx to Predicate Devices

The ProBx software application is substantially equivalent to the predicate device (DynaCAD, K133030) in the areas of technological characteristics such as basic design, function, method of operation, application, and intended use.

Both software:

- operate in Windows and function as a kiosk.
- are able to import DICOM image from various sources and provide 2D and 3D image display.
- are used with a positioning device and interventional hardware.
- register fiducial-tracked instrumentation in relation to the patient anatomy.
- provide verification images of instrumentation placement.
- do not steer or in any way control the positioning of instruments used.
- allow the procedure to be repeated based on operator judgement.
- are intended for use in MR-guided procedures involving the prostate.

ProBx differs slightly from the DynaCAD in the anatomy access point, fiducial placement and type of needle guide hardware. The transperineal approach using a grid in ProBx is used in reference devices (SmartTarget, K170250). The placement of fiducials is accounted for in an equivalent technique of instrumentation registration. Therefore, the new device does not raise any new potential questions related to safety or performance, and is equivalent to the existing legally marketed devices.

Performance Data:

The ProBx software proposed indications for use are supported by preclinical software verification and validation testing. Bench testing was performed using acceptable scientific methods to validate the fiducial registration technique and determine substantial equivalence to the predicate. This includes validation of the software with the ProBx Hardware in a simulated clinical use phantom study that showed our device can achieve end-to end needle placement accuracy of 1.88 mm. This result shows the ProBx Software is non-inferior to the published end-to end needle placement accuracy of DynaCAD.

The following are the referenced standards during design and development of the ProBx Software:

- ISO 15223-1:2016, Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied
- ISO 14971:2007, Medical Devices - Application of Risk Management to Medical Devices
- IEC 62304:2006, Medical Device Software – Software Life Cycle Processes

Conclusion:
ProBx Software has similar indications statements as the predicate device. Both devices are used for MR-guided interventional planning with interventional hardware for procedures involving the prostate. The functionality of the ProBx Software and the predicate device is

identical. The results of software verification and validation testing support that ProBx Software functions as intended when used with ProBx Hardware accessories for prostate interventional procedures. Therefore, ProBx Software is substantially equivalent to the predicate device.