Braid.Health
% Ms. Vivian Liu
Correspondent
301 Rhode Island St.
SAN FRANCISCO CA 94103

August 13, 2020

Re: K200822
Trade/Device Name: Braid
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 16, 2020
Received: July 16, 2020

Dear Ms. Liu:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K200822

Device Name
Braid

Indications for Use *(Describe)*
Braid is a software teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web. Braid is used by hospitals, clinics, imaging centers, and radiologist reading practices.

Braid can optionally be used for mobile diagnostic use for review and analysis of CR, DX, CT, and MR images and medical reports. Braid mobile diagnostic use is not intended to replace full diagnostic workstations and should only be used when there is no access to a workstation. Braid mobile diagnostic use is not intended for the display of mammography images for diagnosis.

When images are reviewed and use as an element of diagnosis, it is the responsibility of the trained physician to determine if the image quality is suitable for their clinical application.

Contraindications: Braid is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel only who are qualified to create and diagnose radiological image data.

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

K200822

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for Braid™ is provided below:

SUBMITTER

Submitter:	Braid.Health 301 Rhode Island St. B10 San Francisco, CA 94103
Contact Person:	Vivian Liu Braid.Health 301 Rhode Island St. B10 San Francisco, CA 94103 vivian@braid.health (617) 335-6866
Date Prepared:	March 27, 2020

DEVICE

Name of Device:	Braid
Common or Usual Name:	Picture archiving and communications system
Classification:	21 CFR 892.2050
Regulatory Class:	Class II
FDA Panel	Radiology
Product Code:	LLZ - System, Image Processing, Radiological

1. PREDICATE DEVICES

	Primary	**Secondary**
Predicate Device Name:	BOX DICOM Viewer™	Enterprise Imaging XERO Viewer 8.1
Manufacturer:	BOX INC.	Agfa HealthCare N.V.
510(k) Number:	K151957	K170434

Reference Devices:	No reference devices are used in this submission.

2. DEVICE DESCRIPTION

Braid is a web-based software platform that allows a user to view DICOM-compliant images for diagnostic and mobile-diagnostic purposes. Braid may be used with FDA-cleared diagnostic monitors and mobile devices including iPhones, and iPads . It is a picture archiving and communication system (PACS), product code LLZ, intended to provide an interface for the display, annotation, and review of reports and demographic information. Braid allows for multi-specialty viewing of medical images including Computed Radiography (CR), Computer Tomography (CT), Digital Radiography (DX), Magnetic Resonance (MR), as well as associated non-imaging data such as report text.

- Braid can be used for primary diagnosis on FDA-cleared diagnostic monitors. Braid is intended for use by trained and instructed healthcare professionals, including (but not limited to) physicians, surgeons, nurses, and administrators to review patient images, perform non-destructive manipulations, annotations, and measurements. When used for diagnosis, the final decision regarding diagnoses resides with the trained physician, and it is up to the physician to determine if image quality is suitable for their clinical application.
- Braid can also be used for reference and diagnostic viewing on mobile devices. Braid diagnostic use on mobile devices is not intended to replace full diagnostic workstations and should only be used only be used for when there is no access to workstation. When used for diagnosis, the final decision regarding diagnoses resides with the trained physician, and it is up to the physician to determine if image quality is suitable for their clinical application.

Braid has the following viewer technology and features:

- Grayscale Image Rendering
- Localizer Lines
- Localizer Point
- Orientation Markers
- Distance Markers
- Study Data Overlays
- Stack Navigation Tool
- Window/Level Tool
- Zoom Tool
- Panning Tool
- Color Inversion
- Text Annotation

- Maximum Intensity Projection
- Reslicing (MPR)
- Area Measurement Annotation
- Angle Measurement Annotation

In addition, Braid has:

- Added Hardware accelerated rendering
- Support for high resolution Retina displays
- Keyboard shortcuts for all tools and all annotation types
- Touchscreen support
- Quick image manipulation and navigation via multitouch gestures, on touchscreens or multitouch capable trackpads

3. INDICATIONS FOR USE

Braid™ is a software teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web. Braid™ is used by hospitals, clinics, imaging centers, and radiologist reading practices.

Braid™ can optionally be used for mobile diagnostic use for review and analysis of CR, DX, CT, and MR images and medical reports. Braid mobile diagnostic use is not intended to replace full diagnostic workstations and should only be used when there is no access to a workstation. Braid™ mobile diagnostic use is not intended for the display of mammography images for diagnosis.

When images are reviewed and use as an element of diagnosis, it is the responsibility of the trained physician to determine if the image quality is suitable for their clinical application.

Contraindications: Braid™ is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel only who are qualified to create and diagnose radiological image data.

4. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1 below compares the key technological features of the subject devices to the predicate devices BOX DICOM Viewer™ (K151957) and Enterprise Imaging XERO Viewer 8.1, (K170434). While there are several differences in the technological features of Braid™ compared to the predicate devices, these differences do not raise new questions of safety and effectiveness and are supported by performance testing in order to establish substantial equivalence.

Table 1: Device Comparison Table

No.	Function	Subject Device (Braid™)	Primary Predicate Device BOX DICOM Viewer™ (K151957)	Secondary Predicate Device Enterprise Imaging XERO Viewer 8.1 (K170434)	Function Comparison
1	Applicant	Braid.Health	OTech, Inc	Agfa HealthCare N.V.	
2	Device Name	Braid™	BOX DICOM Viewer™	Enterprise Imaging XERO Viewer 8.1	
3	Product Code	LLZ	LLZ	LLZ	Same
4	Regulation Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	Same
5	Indications for Use	Braid™ is a software teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web. Braid™ is used by hospitals, clinics, imaging centers, and radiologist reading practices. Braid™ can optionally be used for mobile diagnostic use for review and analysis of CR, DX, CT, and MR images and medical reports. Braid mobile diagnostic use is not intended to replace full diagnostic workstations and should only be used when there is no access to a workstation. BraidTM mobile diagnostic use is not intended for the display of mammography images for diagnosis. When images are reviewed and use as an	The BOX DICOM Viewer™ is a software Teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. The BOX DICOM Viewer™ is used by hospitals, imaging centers, radiologist reading practice. Contraindications: The BOX DICOM Viewer™ is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel only who are qualified to create and diagnose radiological image data.	Agfa HealthCare's Enterprise Imaging XERO Viewer 8.1 is a software application used for reference and diagnostic viewing of multi-specialty medical imaging and non-imaging data with associated reports and documents and, as such, fulfills a key role in the Enterprise Imaging Solution. XERO Viewer 8.1 enables healthcare professionals, including (but not limited to) physicians, surgeons, nurses, and administrators to receive and view patient images, documents and data from multiple departments and organizations within one multi-disciplinary viewer. XERO Viewer 8.1 allows users to perform image manipulations (including window/level, markups, 3D visualization) and measurements. When images are reviewed and use as an element of diagnosis, it is the responsibility of the trained physician to determine if the image	The proposed indications for use are similar to both predicates. The indications include mobile diagnostic indications which are present in the secondary predicate but absent in the primary predicate. Mobile diagnostic use is supported by performance testing in order to establish substantial equivalence.

No.	Function	Subject Device (Braid™)	Primary Predicate Device BOX DICOM Viewer™ (K151957)	Secondary Predicate Device Enterprise Imaging XERO Viewer 8.1 (K170434)	Function Comparison
		element of diagnosis, it is the responsibility of the trained physician to determine if the image quality is suitable for their clinical application. Contraindications: Braid™ is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel only who are qualified to create and diagnose radiological image data.		quality is suitable for their clinical application. Lossy compressed mammography images and digitized film images should not be used for primary image interpretation. Uncompressed or non-lossy compressed "for presentation" images may be used for diagnosis or screening on monitors that are FDA-cleared for their intended use. XERO Viewer 8.1 can optionally be configured for Full Fidelity Mobile, which is intended for mobile diagnostic use, review and analysis of CR, DX, CT, MR, US, ECG images and medical reports. XERO Viewer Full Fidelity Mobile is not intended to replace full diagnostic workstations and should only be used when there is no access to workstation. XERO Viewer Full Fidelity Mobile is not intended for the display of mammography images for diagnosis.	
6	Modalities	CR, DX, CT, MR	CT, MR, US, PET	CR, DX, CT, MR, US, ECG	Braid™ offers a subset of the imaging modalities when compared to the secondary predicate. The absence of these modalities does not raise any issues of substantial equivalence, and performance data is provided to support those modalities that are included.

No.	Function	Subject Device (Braid™)	Primary Predicate Device BOX DICOM Viewer™ (K151957)	Secondary Predicate Device Enterprise Imaging XERO Viewer 8.1 (K170434)	Function Comparison
7	Communication	DICOM	DICOM	DICOM	Same
8	Network Access	Web Browser	Web Browser	Web Browser	Same
9	Web Browser Software	Google Chrome, Safari	Google Chrome for all features. Microsoft Internet Explorer & Mozilla Firefox for features except the DICOM Viewer.	Microsoft Internet Explorer, Google Chrome, Safari, Mozilla Firefox	Similar – each product offers a list of compatible internet browsers. The proposed browsers for Braid are supported by performance testing.
10	Mobile Platforms	iPhones, iPads	None	iPads	Similar – both Braid and Xero have designated mobile platforms that they support. This functionality is supported by performance testing for the intended mobile platforms.
11	User Interface/Input	Mouse and keyboard, Touchscreens	Mouse and keyboard	Mouse and keyboard, Touchscreens	Similar, Braid and Xero both provide touchscreen functionality. This function is supported by performance testing to support substantial equivalence.
12	Drag and Drop Import	Yes	Yes	Yes	Same
13	Image Storage	Yes	Yes	Yes	Same
14	Database Software	CouchDB, IndexedDB, LevelDB	MySQL	unknown	IndexedDB is an alternative to the WebSQL (deprecated) database, and relational databases such as MySQL. Such as LevelDB and CouchDB, it is a key-value pair NoSQL database, which can provide the same functionalities. IndexedDB is now the native and high-performance

No.	Function	Subject Device (Braid™)	Primary Predicate Device BOX DICOM Viewer™ (K151957)	Secondary Predicate Device Enterprise Imaging XERO Viewer 8.1 (K170434)	Function Comparison
					standard in browsers.
15	Grayscale image rendering	Yes	Yes	Yes	Same
16	RGB image rendering	No	Yes	Yes	Braid does not have this feature, but the absence of this feature does not raise questions of safety and effectiveness or affect the intended use of the device.
17	Distance Markers	Yes	Yes	Yes	Same
18	Study Data Overlays	Yes	Yes	Yes	Similar – both Braid and BOX DICOM offer overlays with study data, while Xero includes this information in a header bar. This difference does not impact safety or effectiveness.
19	Stack navigation	Yes	Yes	NA	Same
20	Window Level	Yes	Yes	Yes	Same
21	Zoom in on Image	Yes	Yes	Yes	Same
22	Panning	Yes	Yes	Yes	Same
23	Invert Image	Yes	Yes	Yes	Same
24	Text Annotation	Yes	Yes	Yes	Same
25	MIP/MPR Reconstruction	Yes	No	Yes	Braid offers MIP and MPR reconstruction as does the Xero Viewer predicate. Compared to the BOX predicate this is an additional feature. This feature does not raise new questions of safety

No.	Function	Subject Device (Braid™)	Primary Predicate Device BOX DICOM Viewer™ (K151957)	Secondary Predicate Device Enterprise Imaging XERO Viewer 8.1 (K170434)	Function Comparison
					and effectiveness, but required performance data to support its function.
26	Area Measurement Annotation	Yes	Yes	Yes	Same
27	Angle Measurement Annotation	Yes	Yes	Yes	Same
28	User Interface Text Styles, colors, Fonts and Icons	None	BOX Styles	None	BOX offers custom styling for user preference, whereas the proposed device and Xero do not. This is a user preference that has no impact on safety or effectiveness.
29	WebGL rendering optimization	Yes	Yes	Unknown	Hardware acceleration is used. WebGL (Web Graphics Library) is a JavaScript API for rendering interactive 3D computer graphics and 2D graphics within any compatible web browser without the use of plug-ins. The user of this technology raises no new questions of safety and effectiveness and is supported by performance testing.
30	Support for high resolution Retina display	Full pixel density on all displays	Full pixel density on all displays	Full Fidelity Mode	Both Braid and Box display the full pixel density of the saved image, while the Xero Viewer has an optional full fidelity mode. This difference does not impact safety and effectiveness, as the reduced resolution option on the Xero viewer is just a user preference that may reduce loading times when full fidelity is not desired

No.	Function	Subject Device (Braid™)	Primary Predicate Device BOX DICOM Viewer™ (K151957)	Secondary Predicate Device Enterprise Imaging XERO Viewer 8.1 (K170434)	Function Comparison
31	Keyboard shortcuts	Yes	Yes	Yes	Same

5. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Software Verification and Validation Testing

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.

Mobile Device Bench Testing

Bench testing in accordance with AAPM Report No. 270 - Display Quality Assurance (2019) and AAPM on-line report No. 03, "Assessment of Display Performance for Medical Imaging Systems" was performed to evaluate the ability of the intended mobile device screens to support the proposed indications for use. This testing was conducted on the iPhone 11 and iPad Pro 3. The following display performance characteristics were evaluated:

- Spatial Resolution
- Luminance Response
- DICOM GSDF
- Artifacts
- Temporal Response
- Color & Greyscale Tracking
- Reflection - diffuse
- Reflection - specular
- Ambient Light
- Uniformity

This bench testing demonstrated that the designated hardware platforms are appropriate for Braid™'s intended use and supports substantial equivalence of Braid™ to the predicate devices.

Clinical Validation Testing

Clinical validation testing was conducted to support the diagnostic quality of Braid™ on mobile devices as well as the use of Braid™ features such as reslicing (MPR). Board-certified radiologists were asked to evaluate all braid features and to provide multiple scores for the quality of the Braid™ images on both an FDA-cleared diagnostic monitor as well as the intended mobile devices. Images were evaluated across all intended imaging modalities and in both office and bright lighting conditions. Results demonstrated that the images displayed by Braid™ were of appropriate diagnostic quality in all conditions. These performance data including image quality evaluations by qualified radiologists are adequate to support substantial equivalence of Braid™ to the predicate devices.

6. CONCLUSIONS

Braid™ has the same intended use as a picture archiving and communication system as both predicate devices, BOX DICOM Viewer™ (K151957) and Enterprise Imaging XERO Viewer 8.1 (K170434). Braid™ has similar technological characteristics as both predicates, but differs in some features when compared to each, such as diagnostic use on mobile platforms when there is no access to a diagnostic workstation, the specific imaging modalities, or features such as reslicing. These differences do not raise new questions of safety and effectiveness, but are supported by performance testing including software verification testing, bench testing, and clinical validation testing. Based on the acceptable results of the performance testing, it is determined that Braid™ is substantially equivalent to the predicate devices.