October 30, 2020

Whiterabbit.ai Inc.
% Mr. Jason Su
CTO and Co-founder
3930 Freedom Cir., Ste 101
SANTA CLARA CA 95054

Re: K202013
Trade/Device Name: WRDensity by Whiterabbit.ai
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QIH
Dated: September 29, 2020
Received: September 30, 2020

Dear Mr. Su:

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 and Part 809); 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,

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)*

K202013

Device Name

WRDensity by Whiterabbit.ai

Indications for Use *(Describe)*

WRDensity is a software application intended for use with compatible full field digital mammography and digital breast tomosynthesis systems. WRDensity provides an ACR BI-RADS 5th Edition breast density category to aid interpreting physicians in the assessment of breast tissue composition. WRDensity produces adjunctive information. It is not a diagnostic aid.

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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Section 5. 510(k) Summary

5.1 General Information

K202013

510(k) Sponsor	Whiterabbit AI Inc.
Address	3930 Freedom Cir., Ste 101 Santa Clara, CA 95054
Correspondence Person	Jason Su
Contact Information	914-275-1097 jason@whiterabbit.ai
Date Prepared	October 29, 2020

5.2 Subject Device

Proprietary Name	WRDensity by Whiterabbit.ai
Common Name	WRDensity
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Regulatory Class	II

5.3 Predicate Device

Proprietary Name	Densitas densityai
Premarket Notification	K192973
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Product Code	LLZ
Regulatory Class	II

5.4 Device Description

WRDensity is a standalone software application that automatically analyzes "for presentation" data from digital breast x-ray systems with a deep learning algorithm to assess breast tissue composition. WRDensity primarily generates two outputs for an exam, the Breast Density Level (BDL) and the Breast Density Level Probabilities (BDLP).

The Breast Density Level is a categorical breast density assessment in accordance with the American College of Radiology (ACR) Breast Imaging Reporting and Data System (BI-RADS®) Atlas 5th Edition breast density categories "A" through "D". The BDL is the primary output of WRDensity.

The Breast Density Level Probabilities are the probabilities calculated by WRDensity for each of the four density categories. The BDLP is a secondary output that provides more information about the breast density of an exam and the device's confidence level.

WRDensity takes in images via a Digital Imaging and Communications in Medicine (DICOM) transfer from the facility's mammography imaging system, Picture Archive and Communication Server (PACS), or DICOM router. After analysis, WRDensity sends outputs to be stored in the PACS and Radiology Information System (RIS). These outputs can then be reviewed by the radiologist on the mammography workstation as a DICOM Secondary Capture Image, a DICOM Structured Report, and in the RIS. These outputs can be configured to match user preferences.

5.5 Indications for Use

WRDensity is a software application intended for use with compatible full-field digital mammography and digital breast tomosynthesis systems. WRDensity provides an ACR BI-RADS 5th Edition breast density category to aid interpreting physicians in the assessment of breast tissue composition. WRDensity produces adjunctive information. It is not a diagnostic aid.

5.6 Comparison of Technological Characteristics with the Predicate Device

Table 5.1 Predicate Device Table

	Subject Device WRDensity	**Predicate Device** densityai (K192973)
Classification Name	Automated Radiological Image Processing Software	System, Image Processing, Radiological
Product Code	QIH	LLZ
Regulation Number	892.2050	892.2050
Regulation Description	Picture archiving and communication system	Picture archiving and communication system

Table 5.2 Indications and Technological Characteristics Comparison

	Subject Device WRDensity	**Predicate Device** densityai (K192973)
Indications for Use	WRDensity is a software application intended for use with compatible full field digital mammography and digital breast tomosynthesis systems. WRDensity provides an ACR BI-RADS Atlas 5th Edition breast density category to aid interpreting physicians in the assessment of breast tissue composition. WRDensity produces adjunctive information. It is not a diagnostic aid.	Densitas densityai™ is a software application intended for use with compatible full field digital mammography and digital breast tomosynthesis systems. Densitas densityai™ provides an ACR BI-RADS Atlas 5th Edition breast density category to aid interpreting physicians in the assessment of breast tissue composition. Densitas densityai™ produces adjunctive information. It is not a diagnostic aid.
Patient Population	Symptomatic and asymptomatic women undergoing mammography	Symptomatic and asymptomatic women undergoing mammography
End Users	Interpreting Physicians	Interpreting Physicians
Image Source Modalities	**FFDM** Hologic Selenia Dimensions Hologic Lorad Selenia **Synthetic 2D** Hologic C-View	**FFDM** Hologic Selenia Dimensions Hologic Lorad Selenia GE Senographe Essential GE Senographe Pristina Siemens MAMMOMAT Inspiration Siemens MAMMOMAT Novation DR Siemens MAMMOMAT Fusion Siemens MAMMOMAT Inspiration Prime Siemens MAMMOMAT Revelation

		Synthetic 2D Hologic C-View
Input: Image Data Format	DICOM digital mammography images – For Presentation; RCC, LCC, RMLO, LMLO	DICOM digital mammography images – For Presentation; RCC, LCC, RMLO, LMLO
Output Data	BIRADS 5th Ed. For each patient: Whiterabbit.ai WRDensity Breast Density Level, and Breast Density Level Probability	BIRADS 5th Ed. For each patient: Densitas densityai™ breast density grade
Measurement Scale	4-category breast density scale from 5th Ed. ACR BI-RADS Atlas 2013	4-category breast density scale from 5th Ed. ACR BI-RADS Atlas 2013
Output Device	Mammography Workstation, PACS, RIS	Mammography Workstation, PACS, RIS
Output Format	DICOM Structured Report and Secondary Capture Text labels presented in a radiologist's PACS and RIS patient worklist.	DICOM Structured Report and Secondary Capture
Deployment	Virtual Machine Software	Standalone computer
Assessment Scope	Results per exam	Results per exam
Assessment Type	Image feature-based with deep learning	Image feature-based
Anatomical Location	Breast	Breast

5.7 Performance Data

Safety and performance of WRDensity have been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, software validation activities were performed in

accordance with *IEC 62304:2006/AC:2015 - Medical device software – Software life cycle processes,* in addition to the FDA guidance document, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."*

The validation testing evaluated the performance of WRDensity along a number of dimensions, including:

- Performance was assessed by comparing the Breast Density Level output to the radiologist consensus using accuracy, quadratically-weighted Cohen's kappa, and confusion matrices. Performance on the four-class task and binary task, i.e. dense (BI-RADS C+D) vs. non-dense (BI-RADS A+B) were both assessed.
- Consistency was assessed by evaluating the agreement, in terms of percentage of cases, between the BDL for the mediolateral oblique (MLO) and craniocaudal (CC) views of the same breast.
- Reproducibility was assessed using the maximum root mean square error across all images between the predicted probabilities produced from an initial processing run and those produced in a second processing run on the same testing data.

The output of WRDensity was compared against a consensus of five expert radiologists who independently assessed breast density on a test dataset that represented all compatible modalities and patient populations. The test dataset comprised 871 exams from unique patients. On the four-class task, WRDensity achieved a quadratically-weighted Cohen's kappa of 0.90, 95% confidence interval [0.88, 0.92]. A confusion matrix demonstrating the level of agreement between the BDL and the radiologist consensus for each BI-RADS breast density category can be found in Figure 1.

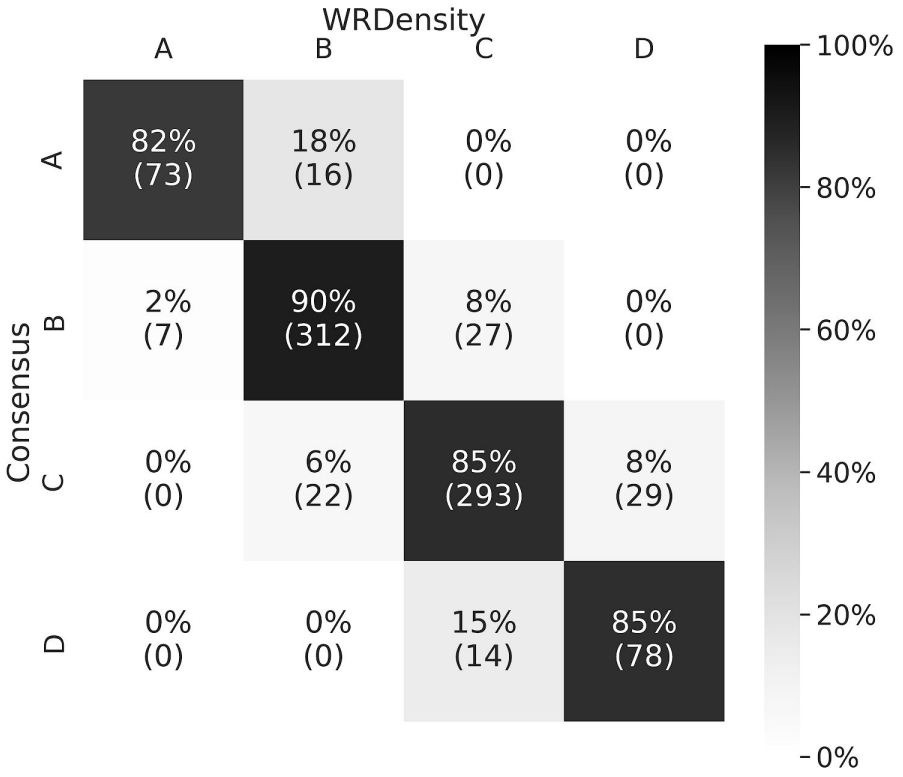

Figure 1: Confusion matrix comparing the performance of WRDensity against the radiologist consensus assessment of breast density for the four-class BI-RADS breast density task. The number of exams within each bin is shown in parentheses.

On the binary task, WRDensity achieved a Cohen's kappa of 0.88, 95% confidence interval [0.85, 0.91]. The confusion matrix is presented in Figure 2.

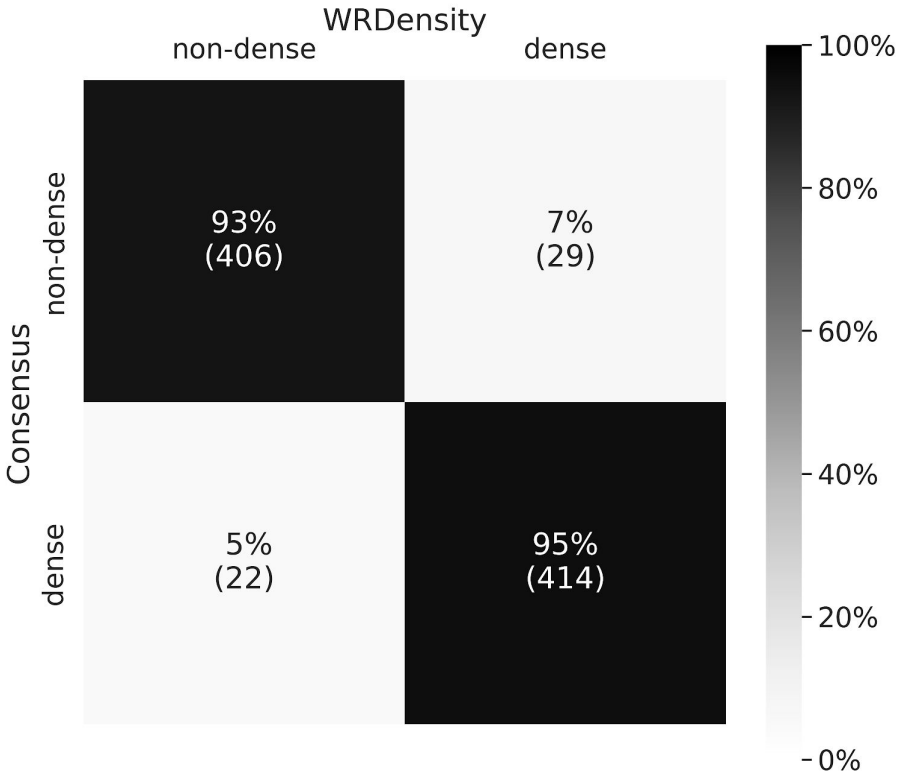

Figure 2: Confusion matrix comparing the performance of WRDensity against the radiologist consensus assessment of breast density for the binary breast density task, dense (BI-RADS C+D) vs. non-dense (BI-RADS A+B). The number of exams within each bin is shown in parentheses.

5.8 Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics, and performance testing, WRDensity raises no new questions of safety or effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.