Behold.AI Technologies Limited
% John J. Smith, M.D., J.D.
Regulatory Counsel
Hogan Lovells US LPP
555 13th Street, NW
WASHINGTON DC 20004

February 28, 2020

Re: K191556
Trade/Device Name: red dot™ Device
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: January 29, 2020
Received: January 29, 2020

Dear Dr. Smith:

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: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*

K191556

Device Name

red dot™ device

Indications for Use

The red dot™ software platform is a software workflow tool designed to aid the clinical assessment of adult Chest X-Ray cases with features suggestive of Pneumothorax in the medical care environment. red dot™ analyzes cases using an artificial intelligence algorithm to identify suspected findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. red dot™ is not intended to direct attention to specific portions of an image or to anomalies other than Pneumothorax. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out Pneumothorax or otherwise preclude clinical assessment of X-Ray cases.

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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behold.ai – 510(k) Summary

Behold.ai **red dot™**

510(k) SUMMARY

Behold.ai Technologies Limited's red dot™

K191556

Submitter

Behold.ai Technologies Limited
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Phone: (+44) 7734 048778

Contact Person: Simon Rasalingham

Date Prepared: January 29, 2020

Name of Device: Behold.ai red dot™ Device
Classification Name: Radiological Computer-Assisted Prioritization Software for Lesions
Regulatory Class: Class II (Radiology)
Product Code: QFM

Predicate Device

The red dot™ device is substantially equivalent to the following device:

Manufacturer Name	Zebra Medical Vision Ltd.
Devices Trade Name	HealthPNX
510(k) Number	K190362

A. Device Description

Behold.ai red dot™ is a radiological computer-assisted triage and notification software system. The software automatically analyzes PA/AP chest x-rays and alerts the PACS/RIS workstation once images with features suggestive of pneumothorax are identified.

Through the use of the red dot™ device, a radiologist is able to review studies with features suggestive of pneumothorax earlier than in standard of care workflow.

In summary, the red dot™ device provides a passive notification through the PACS/workstation to the radiologists indicating the existence of a case that may potentially benefit from prioritization. It doesn't output an image and therefore it does not mark, highlight, or direct users' attention to a specific location on the original chest X ray.

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The device aim is to aid in prioritization and triage of radiological medical images only.

B. Technical Components

The main components of the red dot™ device are described below.

1. Image input, validation and anonymization
After a chest x-ray has been performed, a copy of the study is received and processed by the red dot™ device. Following receipt of a study, the validation feature ensures the image is valid (i.e. has readable pixels) and the anonymization feature removes or anonymizes Personally Identifiable Information (PII) such as Patient Name, Patient Birthdate, and Patient Address.

2. red dot™ Image Analysis Algorithm
This component of the device is primarily comprised of the visual recognition algorithm that is responsible for detecting images with potential abnormalities. Once a study has been validated, the algorithm analyzes the frontal chest x-ray for detection of suspected findings suggestive of pneumothorax.

3. PACS Integration Feature
The results of a successful study analysis is provided to an integration engine in a standard JSON message containing sufficient information to allow the integration engine to notify the PACS/workstation for prioritization through the worklist interface.

C. Intended Use / Indications for Use

The red dot™ software platform is a software workflow tool designed to aid the clinical assessment of adult Chest X-Ray cases with features suggestive of Pneumothorax in the medical care environment. red dot™ analyzes cases using an artificial intelligence algorithm to identify suspected findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. red dot™ is not intended to direct attention to specific portions of an image or to anomalies other than Pneumothorax. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out Pneumothorax or otherwise preclude clinical assessment of X-Ray cases.

D. Summary of Technological Characteristics

Behold.ai red-dot™ tool uses Artificial Intelligence (AI) and pattern recognition technology to analyze chest X-rays. The Behold.ai red-dot™ tool notifies a clinician of the presence of Pneumothorax in a radiological image. The technological characteristics of the red dot™ device and the HealthPNX predicate are compared below:

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Technological Characteristics	Subject Device: Behold.ai red dot™	Predicate Device: Zebra HealthPNX K190362	If different, Impact on Safety and or Efficacy
Indication for use	The red dot™ software platform is a software workflow tool designed to aid the clinical assessment of adult Chest X-Ray cases with features suggestive of Pneumothorax in the medical care environment. red dot™ analyzes cases using an artificial intelligence algorithm to identify suspected findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. red dot™ is not intended to direct attention to specific portions of an image or to anomalies other than Pneumothorax. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out Pneumothorax or otherwise preclude clinical assessment of X-Ray cases.	The Zebra Pneumothorax device is a software workflow tool designed to aid the clinical assessment of adult Chest X-Ray cases with features suggestive of Pneumothorax in the medical care environment. HealthPNX analyzes cases using an artificial intelligence algorithm to identify suspected findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. HealthPNX is not intended to direct attention to specific portions of an image or to anomalies other than Pneumothorax. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out Pneumothorax or otherwise preclude clinical assessment of X-Ray cases	Same
Notification-only, parallel workflow tool	Yes	Yes	Same
Intended user	Hospital networks and trained clinicians	Hospital networks and trained clinicians	Same
Radiological images format	DICOM	DICOM	Same
Identify patients with a pre-specified clinical condition	Yes	Yes	Same
Clinical condition	Pneumothorax	Pneumothorax	Same
Alert to finding	Passive notification flagged for review	Passive notification flagged for review	Same

Technological Characteristics	Subject Device: Behold.ai red dot™	Predicate Device: Zebra HealthPNX K190362	If different, Impact on Safety and or Efficacy
Independent of standard of care workflow	Yes; No cases are removed from worklist	Yes; No cases are removed from worklist	Same
Modality	X-Ray	X-Ray	Same
Body Part	Chest	Chest	Same
Artificial Intelligence algorithm	Yes	Yes	Same
Limited to analysis of imaging data	Yes	Yes	Same
Aids prompt identification of cases with indicated findings	Yes	Yes	Same
Where results are received	PACS / RIS / EPR / Workstation	PACS / Workstation	No significant difference

E. Performance Data

A multi-center IRB approved HIPAA compliant retrospective anonymized study of adult patient CXR images was performed. CXR images positive and negative for pneumothorax were collected consecutively based on the inclusion and exclusion criteria as per protocol.

The final standalone dataset was composed of 888 CXR images from 2 clinical sites from the United States (n=738) and 2 clinical sites from the United Kingdom (n=150). The final standalone dataset included pneumothorax positive (n=299) and negative cases (n=589). Both groups contained confounding imaging features.

Each CXR image was reviewed by at least two ABR certified radiologists (readers). The readers received training related to imaging findings defining each condition per protocol prior to the review. All films were stripped of all identifiers and clinical information. Readers were blinded to each other's reads and to the red dot™ software output. The ground truth was determined by two readers with a third reader in the event of disagreement/discrepancy. Ground truth for a condition was defined as agreement between two readers. The breakdown for the final ground truthed standalone dataset for each site was the following:

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Disease Class	Total Number of Cases	Site 1 Cases	Site 2 Cases	Site 3 Cases	Site 4 Cases
PNX, Non-normal Control, Normal Control	888	419	319	77	73
PNX	299	177	95	14	13
Non-normal Control	167	50	50	36	31
Normal Control	422	192	174	27	29

The AUROC, accuracy, sensitivity and specificity for the detection of pneumothorax, along with the associated 95% confidence intervals are presented below. As shown, the AUROC is above 0.95 and all lower bounds of the 95% confidence intervals exceeded 80% and achieved the pre-specified performance goals in the study.

Pneumothorax (N=888)

- AUROC: 0.975 with 95% confidence intervals [0.966 - 0.984]
- Accuracy: 90.20% (801/888) with 95% confidence interval: [88.06 – 92.08]
- Sensitivity: 94.65% (283/299) with 95% confidence interval: [91.46 – 96.91]
- Specificity: 87.95% (518/589) with 95% confidence interval: [85.04 – 90.46]

Additional Endpoints and Analysis

Clinical data regarding the time saving benefit resulting from use of the device as compared to the standard of care is provided.

Definitions

- **Processing time:** the time taken to process the x-ray image and issue a red dot™ result
- **Notification transit time:** the time taken for the notification to reach the PACS/RIS/EPR worklist after being issued by the red dot™ device
- **red dot™ performance time:** this is equal to the sum of the **processing time** and the **notification transit time**

As described in the definitions list above, the red-dot™ processing time includes the time to receive the DICOM image, upload it to the model inference server, analyze the image and issue the result (PNX notification or no PNX notification) to be sent to the hospital system (RIS or PACS Worklist).

The following table summarizes the red-dot™ processing time in seconds for 888 unique X-rays in the aggregate data.

888 Cases					
Processing Time (seconds)	Mean	Standard Dev	95% Lower Confidence Limit	95% Upper Confidence Limit	Median
red-dot™ processing time	13.8	10.9	13.0	14.5	8.56

The notification transit time is the time taken for the red dot™ notification to travel from the red dot™ device to the point at which the result is displayed in the destination RIS or PACS Worklist. Using data (N=300) established from 3 live customer sites in the UK (100 cases sampled from 3 sites), the average notification transit time in a typical scenario is 15.5 seconds.

When summing the processing time to the notification transit time, the total red dot™ performance time is calculated as 29.3 seconds. This is a timing performance that is substantially equivalent to the Zebra predicate device (K190362, 22.1 seconds). Furthermore, the predicate demonstrated the benefit of triage compared to the standard of care for pneumothorax, meeting the QFM product code requirements.

The red dot™ software device reaching equivalent classification performance (> 0.95 AUC) as well as timing performance to the Zebra predicate device supports that the red dot™ software device can provide equivalent benefit for effective triage as demonstrated by the Zebra predicate device time savings study.

F. Conclusion

Behold.ai red dot™ is as safe and effective as the HealthPNX predicate device. The red dot™ device and the HealthPNX predicate device are both software-only devices intended to aid in triage of radiological images, independent of standard of care workflow. The labeling of both devices are limited to the categorization of exams and are not to be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.

The subject and predicate devices operate in parallel to the standard of care workflow in the sense that they do not change the original image, do not provide any marking, and do not remove cases from the standard of care. The minor differences between the subject device and the predicate raise no new issues of safety or effectiveness. In addition, performance testing demonstrates that the red dot™ performs as intended. The red dot™ device is therefore substantially equivalent to the HealthPNX predicate.