Screenpoint Medical B.V.
℅ Umar Waqas, Ph.D.
Regulatory Officer
Mercator II, 7th floor, Toernooiveld 300
6525 EC Nijmegen, Gelderland
THE NETHERLANDS

December 10, 2019

Re: K192287
Trade/Device Name: Transpara™
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological computer assisted detection and diagnosis software
Regulatory Class: Class II
Product Code: QDQ
Dated: October 30, 2019
Received: November 1, 2019

Dear Dr. Waqas:

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)*
K192287

Device Name
Transpara

Indications for Use *(Describe)*
The ScreenPoint Transpara™ system is intended for use as a concurrent reading aid for physicians interpreting screening mammograms from compatible FFDM systems, to identify regions suspicious for breast cancer and assess their likelihood of malignancy. Output of the device includes marks placed on suspicious soft tissue lesions and suspicious calcifications; region-based scores, displayed upon the physician's query, indicating the likelihood that cancer is present in specific regions; and an overall score indicating the likelihood that cancer is present on the mammogram. Patient management decisions should not be made solely on the basis of analysis by Transpara™.

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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510(k) Summary Transpara™ K192287

This 510(k) summary of safety and effectiveness information is prepared in accordance with the requirements of 21 CFR § 807.92.

1. Submitter

Manufacturer:

ScreenPoint Medical B.V.

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6525 EC Nijmegen

Netherlands

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Mercator II, 7th floor, Toernooiveld 300, 6525 EC Nijmegen, Netherlands

Date:

December 10, 2019

2. Device

Device trade name	Transpara™
Device	Radiological Computer Assisted Detection and Diagnosis Software
Classification regulation	21 CFR 892.2090
Panel	Radiology
Device class	II
Product code	QDQ
Submission type	Traditional 510(k)

3. Legally marketed predicate device

Device trade name	Transpara™ 1.3.0 (K181704)
Legal Manufacturer	ScreenPoint Medical B.V.
Device	Radiological Computer Assisted Detection and Diagnosis Software
Classification regulation	21 CFR 892.2090
Panel	Radiology
Device class	II
Product code	QDQ

4. Device description

Transpara™ is a software-only device for aiding radiologists with the detection and diagnosis of breast cancer in mammograms. The product consists of a processing server and an optional viewer. The software applies algorithms for recognition of suspicious calcifications and soft tissue lesions, which are trained with large databases of biopsy proven examples of breast cancer, benign lesions and normal tissue. Processing results of Transpara™ can be transmitted to external destinations, such as medical imaging workstations or archives, using the DICOM mammography CAD SR protocol. This allows PACS workstations to implement the interface of Transpara™ in mammography reading applications.

Transpara™ automatically processes mammograms and the output of the device can be used by radiologists concurrently with the reading of mammograms. The user interface of Transpara™ has different functions:

a) Activation of computer aided detection (CAD) marks to highlight locations where the device detected suspicious calcifications or soft tissue lesions. Only the most suspicious soft tissue lesions are marked to achieve a very low false positive rate.
b) Regions can be queried using a pointer for interactive decision support. When the location of the queried region corresponds with a finding of Transpara™ a suspiciousness level of the region computed by the algorithms in the device is displayed. When Transpara™ has identified a corresponding region in another view of the same breast this corresponding region is also displayed to minimize interactions required from the user.
c) Display of the exam based Transpara™ Score which categorizes exams on a scale of 1-10 with increasing likelihood of cancer.

Transpara™ is configured as a DICOM node in a network and receives its input images from another DICOM node, such as a mammography device or a PACS archive. The image analysis unit includes machine learning components trained to detect calcifications and soft tissue lesions and a component to pre-process images in such a way that images from different vendors can be processed by the same algorithms.

5. Indications for use

Transpara™ is a software medical device for use in a healthcare facility or hospital with the following indications for use:

> *The ScreenPoint Transpara*™ system is intended for use as a concurrent reading aid for physicians interpreting screening mammograms from compatible FFDM systems, to identify regions suspicious for breast cancer and assess their likelihood of malignancy. Output of the device includes marks placed on suspicious soft tissue lesions and suspicious calcifications; region-based scores, displayed upon the physician's query, indicating the likelihood that cancer is present in specific regions; and an overall score indicating the likelihood that cancer is present on the mammogram. Patient management decisions should not be made solely on the basis of analysis by Transpara™.

Intended user population

Intended users of *Transpara*™ are physicians qualified to read screening mammograms.

Intended patient population

The device is intended to be used in the population of women undergoing screening mammography.

Warnings and precautions

Transpara™ is an adjunct tool and not intended to replace a physicians' own review of a mammogram. Decisions should not be made solely based on analysis by Transpara™.

6. Predicate device comparison

The indication for use of Transpara™1.5.0 is the same as that of the predicate device. Both devices are intended to be used by clinicians interpreting mammograms, to help them with localizing and characterizing abnormalities. The devices are both intended to be used concurrently with the reading of images and are not intended as a replacement for the review of a clinician or their clinical judgement.

The overall design of Transpara™1.5.0 is similar to that of the predicate device. The main differences in technological characteristics of Transpara™ 1.5.0 and the predicate device are algorithmic improvements leading to better detection performance. Additionally, the 1.5.0 version now supports Fujifilm modalities. These changes do not raise different questions of safety and effectiveness.

7. Summary of non-clinical performance data

In the design and development of Transpara™, ScreenPoint applied the following voluntary FDA recognized standards and guidelines:

Standard ID	Standard Title	FDA Recognition #
ISO 14971:2007	Medical Devices - Application Of Risk Management To Medical Devices	5-40
IEC 62304:2015	Medical Device Software - Software Life Cycle Processes	13-79
DEN180005	Decision summary with special controls for class II radiology device	

The following guidance documents were used to support this submission:

- Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Issued on May 11, 2005)
- Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data – Premarket Notification [510(k)] Submissions (Issued on July 3, 2012)
- Guidance for Industry and FDA Staff - Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions (Issued on July 3, 2012)

Software performance testing

Transpara™1.5.0 is a software-only device. The level of concern for the device is determined as Moderate Level of Concern.

Verification testing consisted of software unit testing, software integration testing and software system testing. The verification test showed that the software application satisfied the software requirements.

Validation testing consisted of determining stand-alone performance of the algorithms in Transpara™ using a multi-vendor test-set of mammograms acquired from multiple centers. This test dataset was not used for training of Transpara™ algorithms and included mammograms of asymptomatic women acquired with devices from five manufacturers: Hologic, GE, Philips, Siemens, and Fujifilm. Validation testing confirmed that algorithm performance has improved in comparison to Transpara 1.3.0 for the four manufacturers for which the device was already cleared and that for Fujifilm a similar performance is achieved.

Based on results of verification and validation tests it is concluded that Transpara™ is effective in the detection of soft lesions and calcifications at an appropriate safety level in mammograms acquired with mammography devices for which the software has been validated.

8. Summary of clinical tests

A pivotal reader study was conducted with the predicate device Transpara 1.3.0. This study provided evidence for safety and effectiveness of Transpara™.

9. Conclusions

The data presented in this 510(k) includes all required information to support the review by FDA. Standalone performance tests demonstrate that Transpara™ 1.5.0 achieves better detection performance compared to the predicate device.

ScreenPoint has applied a risk management process in accordance with FDA recognized standards to identify, evaluate, and mitigate all known hazards related to Transpara™. These hazards may occur when accuracy of diagnosis is potentially affected, causing either false-positives or false-negatives. All identified risks are effectively mitigated and it can be concluded that the residual risk is outweighed by the benefits.

Considering all data in this submission, the data provided in this 510(k) supports the safe and effective use of Transpara™ for its indications for use and substantial equivalence to the predicate device.