



March 5, 2020

ScreenPoint Medical B.V.  
% Umar Waqas, Ph.D.  
Head of Regulatory and Quality Affairs  
Mercator II, 7th floor, Toernooiveld 300  
6525EC Nijmegen, Gelderland  
THE NETHERLANDS

Re: K193229

Trade/Device Name: Transpara™ 1.6.0  
Regulation Number: 21 CFR 892.2090  
Regulation Name: Radiological computer assisted detection and diagnosis software  
Regulatory Class: Class II  
Product Code: QDQ  
Dated: January 28, 2020  
Received: February 3, 2020

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](mailto: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

## Indications for Use

510(k) Number (if known)  
K193229

Device Name  
Transpara™ 1.6.0

### Indications for Use (Describe)

Transpara™ software is intended for use as a concurrent reading aid for physicians interpreting screening full-field digital mammography exams and digital breast tomosynthesis exams from compatible FFDM and DBT systems, to identify regions suspicious for breast cancer and assess their likelihood of malignancy. Output of the device includes locations of calcifications groups and soft-tissue regions, with scores indicating the likelihood that cancer is present, and an exam score indicating the likelihood that cancer is present in the exam. 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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary Transpara™

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.

Mercator II, 7th floor

Toernooiveld 300

6525 EC Nijmegen

Netherlands

[www.screenpoint-medical.com](http://www.screenpoint-medical.com)

### **Contact person:**

Umar Waqas

Office: +31 24 3030045 | +31 24 2020020

Mobile: +31 6 44077104

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

### **Date:**

January 28, 2020

## 2. Device

Device trade name	Transpara™ 1.6.0
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 application designed to be used by physicians to improve interpretation of digital mammography and digital breast tomosynthesis. The system is intended to be used as a concurrent reading aid to help readers with detection and characterization of potential abnormalities suspicious for breast cancer and to improve workflow. ‘Deep learning’ algorithms are applied to FFDM images and DBT slices for recognition of suspicious calcifications and soft tissue lesions (including densities, masses, architectural distortions, and asymmetries). Algorithms are trained with a large database of biopsy-proven examples of breast cancer, benign abnormalities, and examples of normal tissue.

*Transpara™* offers the following functions which may be used at any time during reading (concurrent use):

- a) Computer aided detection (CAD) marks to highlight locations where the device detected suspicious calcifications or soft tissue lesions.

- b) Decision support is provided by region scores on a scale ranging from 0-100, with higher scores indicating a higher level of suspicion.
- c) Links between corresponding regions in different views of the breast, which may be utilized to enhance user interfaces and workflow.
- d) An exam score which categorizes exams on a scale of 1-10 with increasing likelihood of cancer. The score is calibrated in such a way that approximately 10 percent of mammograms in a population of mammograms without cancer falls in each category.

Results of *Transpara*<sup>™</sup> are computed in processing server which accepts mammograms or DBT exams in DICOM format as input, processes them, and sends the processing output to a destination using the DICOM protocol in a standardized mammography CAD DICOM format. Use of the device is supported for images from the following modality manufacturers: FFDM (Hologic, Siemens, General Electric, Philips, Fujifilm) and DBT (Hologic, Siemens). Common destinations are medical workstations, PACS and RIS. *Transpara*<sup>™</sup> is offered as a virtual machine and runs on pre-selected standard PC hardware as well as a dedicated virtual machine cluster. The system can be configured using a service interface. Implementation of a user interface for end users in a medical workstation is to be provided by third parties.

## 5. Indications for use

*Transpara*<sup>™</sup> is a software medical device for use in a healthcare facility or hospital with the following indications for use:

*Transpara*<sup>™</sup> software is intended for use as a concurrent reading aid for physicians interpreting screening full-field digital mammography exams and digital breast tomosynthesis exams from compatible FFDM and DBT systems, to identify regions suspicious for breast cancer and assess their likelihood of malignancy. Output of the device includes locations of calcifications groups and soft-tissue regions, with scores indicating the likelihood that cancer is present, and an exam score indicating the likelihood that cancer is present in the exam. Patient management decisions should not be made solely on the basis of analysis by *Transpara*<sup>™</sup>.

### Intended user population

Intended users of *Transpara*<sup>™</sup> are physicians qualified to read screening mammography exams and digital breast tomosynthesis exams.

### Intended patient population

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

## 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™ 1.6.0 is similar to that of the predicate device. Both devices are intended for concurrent use by physicians interpreting breast images to help them with localizing and characterizing abnormalities. The devices are not intended as a replacement for the review of a physician or their clinical judgement. Support for DBT has been added in the indications for use of the subject device compared to the indications for use of the predicate device. The algorithmic components have been updated to improve detection accuracy for FFDM and to enable processing of DBT. The subject device also supports Fujifilm FFDM systems, which was cleared in K192287 (Transpara™ 1.5.0).

The overall design of Transpara™ 1.6.0 is the same as that of the predicate device. Both versions detect and characterize findings in radiological breast images and provide information about the presence, location, and characteristics of the findings to the user in a similar way.

Changes do not raise different questions of safety and effectiveness of the device when used as labeled.

## 7. Summary of non-clinical performance data

In the design and development of Transpara 1.6.0, 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)

Transpara™ 1.6.0 is a software-only device. The level of concern for the device is determined as Moderate Level of Concern.

### **Stand-alone performance testing**

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.

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 1.6.0 using an independent multi-vendor test-set of mammography and DBT exams acquired from multiple centers. This test dataset included mammography and DBT exams of women undergoing mammography acquired with devices from five manufacturers: Hologic, GE, Philips, Siemens, and Fujifilm. Validation testing confirmed that algorithm performance is non-inferior or better in comparison to Transpara 1.3.0 for the four manufacturers for which the device was already cleared and that for Fujifilm performance was non-inferior to the performance achieved on the pooled test data of devices cleared for use with the predicate device.

Based on results of verification and validation tests it is concluded that Transpara 1.6.0 is effective in the detection of soft lesions and calcifications at an appropriate safety level.



## 8. Summary of clinical tests

A pivotal reader study was conducted with Transpara 1.6.0. This study was designed to provide evidence for safety and effectiveness of the device.

The objective of the reader study was to determine whether the performance of radiologists detecting breast cancer in DBT exams increases when they concurrently use Transpara compared to when they read DBT exams unaided. In the study, both conditions are tested with a fully-crossed, multi-reader multi-case retrospective study performed by eighteen MQSA qualified radiologists. The study was conducted with an enriched sample of 240 Siemens Mammomat DBT exams, including 65 exams with breast cancer, 65 exams with benign abnormalities, and 110 normal exams.

The primary hypothesis for the study was superior breast-level area under the receiver operating characteristic curve (AUC, ROC) between conditions when radiologists use Transpara™ to read DBT exams at a significance level alpha 0.05.

Secondary objectives of the reader study were to determine if the use of Transpara™ as an aid leads to: 1) reading time reduction, 2) non-inferior or higher sensitivity, 3) non-inferior or higher specificity, and 4) reading time reduction on normal exams. In addition, it was tested if standalone AUC performance of Transpara™ was non-inferior to the average AUC performance of the readers.

Statistical analysis of the reader study results showed that the primary objective and all pre-specified endpoints of the study were met. Radiologists significantly improved their detection performance when using Transpara™ to read DBT exams, with the average AUC increasing from 0.833 to 0.863 ( $P = 0.0025$ ), while reading time was significantly reduced and superior sensitivity was obtained with Transpara™.

Results of the clinical study provide evidence for safety and effectiveness of Transpara™ when used in accordance with the indications for use.

## 9. Conclusions

The data presented in this 510(k) includes all required information to support the review by FDA. Standalone performance tests with FFDM demonstrate that Transpara™ 1.6.0 achieves non-inferior or better detection performance compared to the predicate device. For application with DBT, a clinical reader study and standalone tests demonstrate that the device is safe and effective.

ScreenPoint has applied a risk management process in accordance with FDA recognized standards to identify, evaluate, and mitigate all known hazards related to Transpara 1.6.0. 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 1.6.0 for its indications for use and substantial equivalence to the predicate device.