Meridian Technique Ltd
% Mr. Dave Yungvirt
CEO
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
MILLBURN NJ 07041

October 18, 2017

Re: K171068
Trade/Device Name: OrthoView 7.2
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 9, 2017
Received: October 12, 2017

Dear Mr. Yungvirt:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K171068

Device Name
ORTHOVIEW 7.2

Indications for Use *(Describe)*

OrthoView is indicated for use when a suitable licensed and qualified healthcare professional requires access to medical images with the intention of using such images to plan or review a surgical procedure. OrthoView provides a set of tools and templates (representing prosthetic and fixation devices) to assist the healthcare professional in planning their surgery. The device is not to be used for mammography.

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

Date Summary Prepared: October 16, 2017

The following section is included as required by the Safe Medical Devices Act (SMDA) of 1990 and 21CFR 807.92.

Submitter information

Table 1

Submitter Company & Manufacturer	Meridian Technique Ltd
Establishment registration number	3004537781
Street Address	2 Venture Road, Southampton Science Park
City	Southampton
Postal code	SO16 7NP
Country	UK
Phone number	+44(0) 2380 119663
Principal Contact person	Barbara March
Contact title	Quality Manager
Contact e-mail address	Barbara.march@orthoview.com
Additional contact person	Andy Enefer
Contact title	Engineering Manager
Contact e-mail address	Andy.enefer@orthoview.com

Submission information

THE DEVICE

Table 2

The Device Which Is The Subject Of This Submission	
Device Trade/Proprietary Name	OrthoView 7.2
Device Classification	Class II
Device Panel	Radiology
Common Name	Image Processing System Radiological
Classification Name	Picture Archiving and Communication Systems
Primary product code	LLZ (21 CFR § 892.2050)

THE PREDICATE DEVICE

The Legally Marketed Predicate Device [807.92(a)(3)]

To demonstrate substantial equivalence of OrthoView 7.2 to a device currently cleared for marketing in the USA, Meridian Technique Ltd will utilize the following device which has not been subject to a design-related recall:

Table 3

The Orthopaedic Predicate Device To Which Substantial Equivalence Is Claimed	
Manufacturer	Meridian Technique Ltd
Device Trade/Proprietary Name	OrthoView 4
Device Class	Class II
Device Panel	Radiology
Common Name	Image Processing System Radiological
Classification Name	Picture Archiving and Communication Systems
Primary product code	LLZ (21 CFR § 892.2050)
510(k) number	K063327
Decision date	22nd November 2006

THE DEVICE DESCRIPTION [807.92(a)(4)]

OrthoView 7.2 is dedicated, digital, pre-operative planning and templating software used to create detailed pre-operative plans quickly and easily from digital x-ray images. OrthoView 7.2 is software to be used for medical purposes, performing these purposes without being part of a hardware medical device.

The device provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images.

Conditions of Use

- OrthoView 7.2 is either a standalone device or is provided for use specifically with third party PACS equipment.
- OrthoView 7.2 may be installed on each workstation or deployed onto a workstation from a central server.
- The OrthoView 7.2 software has no direct or indirect patient-contacting components and makes no intentional contact with the patient or any other persons.
- The OrthoView 7.2 software may communicate with a third party source of digital X Ray images and may therefore be connected to a proprietary network.
- Some optional features require Internet access but OrthoView 7.2 can be used without such access.

Service and Maintenance Technicians will be required to:

- Install initial software and software enhancements.
- Maintain access codes and rights.
- Install Templates and Licenses.

The scope for contact is the same as for the Operator.

Table 4

Minimum Operating System Requirements	
Computer	PC or MAC compatible computer
Operating System MAC OS	OS X 10.12 or higher
Operating System Windows	Windows 7, 8, 8.1 or 10
Processor	1 GHz CPU
Memory	2GB RAM
Free Hard Disc Space	2GB free disk space
Graphics/Display	1280 x 1024 colour graphics display
(Optional) Intranet Connection to PACS.	100MBit/Sec
(Optional) Internet Connection (required for case management, auto template update and anonymous stat collection features only).	2MBit/Sec.

Note –this is a minimum requirement for OrthoView 7.2 and NOT for the associated PACS system with which it is operating. It is expected that the associated PACS system will exceed this specification.

INTENDED USE & INDICATIONS FOR USE:

The subject of this submission - OrthoView 7.2

Orthoview is indicated for use when a suitable licensed and qualified healthcare professional requires access to medical images with the intention of using such images to plan or review a surgical procedure. OrthoView provides a set of tools and templates (representing prosthetic and fixation devices) to assist the healthcare professional in planning their surgery.
The device is not to be used for mammography.

***Table 5 – Comparison and Explanation of the Instructions For Use Differences* [807.92(a)(5)]**

Feature	OrthoView 7.2 Device for premarket notification	Predicate Device – OrthoView 4 FDA marketing clearance K063327 following 510(k) submission November 2006
Indications for Use	The Intended use of OrthoView 7.2 is when a suitably licensed and qualified healthcare professional requires access to medical images with the intention of using such images for pre-operative planning of a potential surgical procedure. OrthoView 7.2 is indicated for use when a suitably licensed and qualified healthcare professional requires access to medical images with the intention of using such images to plan or review a surgical procedure. OrthoView 7.2 provides a set of tools and templates (representing prosthetic and fixation devices) to assist the healthcare professional in planning their surgery. The device is not to be used for mammography	OrthoView 4 has the identical intended use and uses identical software and algorithms to achieve this purpose OrthoView 4 is indicated for use when a suitably licensed and qualified healthcare professional requires access to medical images with the intention of using such images, in conjunction with templates for prosthetic and fixation devices, for the purposes of choosing the nature and characteristics of the prosthetic/fixation device to be used when planning a potential surgical procedure. In addition, Trauma and Osteotomy modules and Trauma Templates are provided to extend the range of functionality available to the healthcare professional.

Table 5 – Comparison and Explanation of the Instructions For Use Differences **[807.92(a)(5)]**

Feature	OrthoView 7.2 Device for premarket notification	Predicate Device – OrthoView 4 FDA marketing clearance K063327 following 510(k) submission November 2006
Discussion	The indications for use have been changed to reflect accurately the usage of the device and the predicate. The wording has been slightly changed to reflect that surgeons can plan surgery using either device without actually using a prosthetic or fixation device. Either device allows the healthcare professional to use a set of wizards to make measurements and angles between anatomical landmarks. While these measurements and angles are often used to choose the nature and characteristics of a prosthetic/fixation device they are sometimes sufficient output in themselves for the surgical plan and so a surgeon may use the device without applying templates/fixation devices. Several procedures within the predicate and new device do not require templates/fixation devices to be used. Review has also been added since a healthcare professional may use OrthoView 7.2 or the predicate device to review the plan or surgery of another surgeon by viewing it within the device. The indications for use have therefore been modified to provide a more accurate usage statement allowing for situations whereby the full feature set is not required in order to produce a viable plan for some procedures. In addition, the sentence added in the predicate device submission has been removed. This is because the additional features mentioned are already completely covered in the rest of the indications for use (they were originally added to the predicate device to highlight the extension of functionality in OrthoView 4 added since its previous 510K). Despite the change of wording the new device is substantially equivalent to the predicate device in that there is no change in usage but a clarification of possible and permissible current usage.	

The Application Of The Device And The Intended Patient Population [807.92(a)(5)]

The anatomical site selected and the corresponding image presented by the device are decided and chosen by the physician.

It is evident that the decision regarding whether a patient is included in the target population for either application resides with the patient's physician only and hence, neither application of the device has any direct influence on the target patient population. It is therefore beyond the scope of OrthoView 7.2 to specify an anatomical site or target population other than 'any'.

Technological Characteristics [807.92(a)(6)]

OrthoView 7.2 is medical device software that permits the pre-planning of surgical procedures by permitting image viewing and manipulation within a PACS computer or standalone environment. It is designed to integrate into a third-party provided PACS hardware and software environment. This implies the provision of a computer specification appropriate to a PACS environment. OrthoView 7.2 can be configured to be launched from within a networked environment or as a standalone application. The device is intentionally non-patient contacting patient and does not deliver medication or therapeutic treatment. Energy used or delivered to the user is associated with the related workstation only and not the device.

Performance Data:

Conformance Standards & Guidances

The device complies with the following international and FDA-recognized consensus standards and FDA guidance documents:

- ISO 14971:2012 & ISO14971:2007 Medical devices – Application of risk management to medical devices
- NEMA PS 3.1 – 3.20 (2016), Digital Imaging and Communication in Medicine (DICOM)
- IEC 62304:2006 Medical device software – Software life cycle processes
- IEC 62336:2015, Medical devices - Application of usability engineering to medical devices
- ISO-15223-1:2012-Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling And Information, Part 1 General Requirements
- ISO 14155:2011 - Clinical Investigation of Medical Devices for Human Subjects. Good Clinical Practice
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- Guidance for the Submission of Premarket Notifications for Medical Image Management Devices
- Applying Human Factors and Usability Engineering to Medical Devices

Testing

A full test report is provided for each completed test. The test report includes the objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary and conclusions.

The feature tests of the predicate device now form the regression tests of the subject device verifying that OrthoView 7.2 includes the same functionality as the predicate device.

Non-clinical tests [807.92(b)(1)]

Each release over time has experienced thorough testing and each new release has had its clinical features evaluated by a surgeon (within a non-clinical environment).

Non-clinical testing was performed to determine substantial equivalence. This non-clinical testing included the regression tests associated with the predicate device. Testing verified that the accuracy and performance of the system is adequate and performs as intended.
This software has been extensively verified via code reviews, automated and manual testing.

All manual testing is performed on a fully configured system installed on hospital representative environments using procedure-specific images to emulate as close as possible intended use. All new features are checked by a surgeon to verify clinical performance.

Feature additions since the OrthoView 4 have been verified as being within the scope of the intended use of the predicate. In this way, data generated from each test supports the finding of substantial equivalence.

Substantial Equivalence

The characersitics of the device and the predicate device allow the healthcare professional to use a set of wizards to make measurements and angles between anatomical landmarks. These measurements and angles may be used to choose the nature and characteristics of a prosthetic/fixation device and they are also sufficient output for a surgical plan. OrthoView 7.2 and the predicate device also allow the healthcare professional to review the plan of another surgeon by viewing it within the device.

Functional Comparison

Table 6

TECHNOLOGICAL COMPARISON Physical Properties	
OrthoView 7.2 (this submission)	OrthoView 4 (Predicate Device)
System Requirements- **IDENTICAL** Windows 7, 8.1, 8 or 10, MAC OS X 10.12+ 2GB RAM 2GB Free Disk Space 1280 x 1024 Colour Graphics Display Although the System requirements have changed they are aligned with the improved hardware available in hospitals since release of the predicate device. The current operating environment is identical in that it reflects the availability of Desktop devices to the clinicians in the intended use. Although MAC is a new Operating System it is in keeping with meeting the needs of the clinicians using the device.	Windows XP or Windows 2000 512MB RAM (1GB Recommended) 100Mb Free disk Space 1024x768 Colour Graphics Display
Installation - **IDENTICAL** There is no change to the delivery installation, licensing and integrations of OrthoView.	To be downloaded from the Internet, installed and unlocked using a license provided by Meridian Technique Ltd
Launch - **IDENTICAL** The means of launching OrthoView 7.2 are identical to the predicate device.	Can be configured to be launched from within a PACs workstation environment or as a standalone application.
Login - **IDENTICAL** Access/Login rights are identical but now include the capability to use Hospital enforced access rights through Active Directory.	Grant access rights only to authorized users (via PC password system).

TECHNOLOGICAL COMPARISON Physical Properties	
OrthoView 7.2 (this submission)	OrthoView 4 (Predicate Device)
Image Loading - **IDENTICAL** The Image loading is identical and the expected modalities are also unchanged.	Receive X-Ray images in a digital format from third party X-Ray machines/ X-Ray digitisers or PACS systems. Orthoview 4 provides the means of recording, storing and retrieving the templating process steps performed by the licensed medical professional when assessing the optimum prosthetic device for a particular patient.
Image Manipulation - **IDENTICAL** Image manipulation functionality such as Window/level/flip etc is identical. The function of the existing 90 degree rotation tools has been extended to horizontal and vertical alignment. Templates may now be obtained through an online server.	Orthoview 4 permits to pre-plan surgical procedures by permitting image viewing and manipulation and prosthetic template overlay within a PACS workstation or standalone environment. Orthoview 4 processes such images securely with respect to patient confidentiality, patient identification and image integrity and allows the image to be retrieved for processing as follows: Scaling of the image. Selection of appropriate prosthetic and fixing device manufacturer and size range templates. Overlaying the template on the image and permitting selection of appropriate size of prosthetic/fixing. Provide additional functionality in the form of Trauma Wizards, Pediatrics Wizards Osteotomy Wizards, Fracture Reduction Tools and Trauma Templates Print and archive appropriate reports. Receive and store templates for prostheses and fixations supplied by Meridian for particular manufacturers' range of products. Provide traceability of operator, date and pre-operative plans.
Scaling - **IDENTICAL** The workflow and practice of scaling remains unchanged.	A marker (not included) is a radio-opaque object of known size which is placed on the patient in the same plane as the joint being imaged. Using markers is a more accurate method to confirm oversize but a rudimentary ruler scaling tool is also available to establish pixel spacing on the x-ray, in the event that this information is not present on the image.
Analysis Methods - **IDENTICAL** Different methods of analysing data for the pre-operative plan are now available to the user. The mechanism for selecting the analysis methods and wizards are the same, only the presentation of the relevant wizards has been improved.	The analysis or report summary is generated by the Report Wizard available from the GUI which offers the options of printing and or saving the analysis of the pre-operative plan**.**

TECHNOLOGICAL COMPARISON Physical Properties	
OrthoView 7.2 (this submission)	OrthoView 4 (Predicate Device)
Landmarks - **IDENTICAL** The mechanism for identifying landmarks on an x-ray is identical. The clinical relevance of these points is the same	Various Wizards are available to identify the relevant anatomical points or landmarks according to the clinical procedure being planned.
Contours - **IDENTICAL** Contours are identical to the wizards used in the predicate device to define cut areas in Limb Deformity etc.	Various wizards are available for assessment, planning and reduction for centre of rotation and angulation in planning limb deforinty correction
Cut Positions - **IDENTICAL** Cut positioning functionality is identical to the wizards used in the predicate device for osteotomies etc.	The Osteotomy wizard defines the position and angle of cut required when straightening a shaft.
Reduction - **IDENTICAL** No change to this functionality.	Various Reduction tools and wizards are available for manipulating image fragments and specialized animators for limb deformity procedures
Measurements - **IDENTICAL** The Measurement technology and function is identical to the predicate device. There is no difference to the importance or likelihood of error from these measurements.	The many joint specific wizards rely on measurements in order to correctly pre-plan surgery
Reporting - **IDENTICAL** The reporting function is identical with the added improvement of an analysis specific display.	Orthoview 4 provides the means of recording, storing and retrieving the templating process steps performed by the licensed medical professional when assessing the optimum prosthetic device for a particular patient.
Saving/Commit - **IDENTICAL** The Save & Commit functions are identical.	An OrthoView 4 planning session can be 'Saved' or 'Committed'. 'Saving' a session allows it to be re-opened for review. 'Committing' creates a permanent, read-only record.
Image Storage – **IDENTICAL** Images are still stored permanently in PACS Systems and may be stored temporarily in files. OrthoView 7.2 allows those temporary plans to be stored as files within a Case Management System if desired.	Images are permanently stored within PACS systems within the Hospital. Interim plans may be stored and transported as files.

Risk Analysis

A Risk Analysis has been completed for the device in accordance with ISO14971:2007 and risk control measures have been implemented to mitigate identified hazards, including those resulting from intentional or inadvertent misuse of the device. Any risks posed by the design, manufacture and use of OrthoView 7.2 have been evaluated. The risk analysis indicates that the subject device has the same risk profile in the patient environment, using the same materials and construction principles as the predicate device. Accordingly, it is believed that no further clinical work is required.

Safety and Effectiveness

OrthoView has been in commercial distribution since 2001, has never been the subject of a recall or medical device report and has proven to be safe and effective in clinical usage. Each release has been thoroughly tested and the clinical features have been evaluated by a surgeon (within a non-clinical environment).

Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics, performance testing and technological comparison, OrthoView 7.2 raises no new questions of safety and effectiveness and is substantially equivalent to the predicate devices in terms of safety, efficacy and performance.
