Medical Templates AG
℅ Shawnnah Monterrey
BeanStock Consulting
8885 Rio San Diego Dr. #237
San Diego, CA 92108 USA

Re: K240620 March 25, 2024

Trade/Device Name: Cube Navigator
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 5, 2024
Received: March 5, 2024

Dear Shawnnah Monterrey:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging Devices and Electronic Products
OHT 8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240620

Device Name

Cube Navigator

Indications for Use *(Describe)*

Cube Navigator is a non-invasive software intended for planning the needle trajectory of CT-guided, percutaneous punctures using DICOM-images and a Navigation Cube attached to a patient. It is indicated for the planning the needle trajectory of CT-guided, percutaneous punctures for therapeutic and diagnostic purposes. The software's functionality allows to automatically recognize orientation, position and type of the Navigation Cube present in the DICOM-images and to manually define virtual needle trajectories to a physician-identified target through the Navigation Cube. Based on this planning, Cube Navigator provides physician information for such purpose.

Cube Navigator can only be used in combination with a Navigation Cube, specifically, either the Access Cube for instruments 10-20G (article number mt-ac-ct-20, Class 1 exempt, product code GDF) or the Puncture Cube for instruments 18-22G (article number mt-pc-ct-25, Class 1 exempt, product code GDF). Cube Navigator is a standalone software that integrates the CE-marked and FDA-cleared diagnostic Medical Imaging Viewer medDream manufactured by Softneta that provides all DICOM-related functionality like displaying and manipulating DICOM-images.

The Cube Navigator is intended for interventional radiologists, who perform CT-guided interventions for therapeutic and diagnostic purposes. The intended use environment is the CT control room, which can be in a hospital or a medical office.

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.

K240620 510(k) Summary

Prepared on: 2024-03-20

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medical Templates AG
Applicant Address	Brunnenwiese 10 Egg 8132 Switzerland
Applicant Contact Telephone	+41 43 50 88 59
Applicant Contact	Mr. Joscha Hüttel
Applicant Contact Email	jh@medicaltemplates.ch

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Cube Navigator
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Product Code	LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K141745	IQQA-BODYIMAGING SOFTWARE	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

Cube Navigator is a non-invasive medical device software used in interventional radiology for planning the needle trajectory of CT-guided, percutaneous punctures. Cube Navigator provides planning functionality for needle placement through a separate device, called a Navigation Cube. Cube Navigator allows the user to register the Navigation Cube in a loaded data set and plan a feasible needle trajectory using a virtual needle. Based on this planned trajectory, Cube Navigator displays needle depth and the entry points on the Navigation Cube in its user interface. The Cube Navigator software is only used for planning the needle trajectory, but requires a CT-scan with a Navigation Cube mounted on a patient for the purposes of visualization.

Navigation Cubes are sterile, disposable needle guides which are attached to the patient before the planning scan is acquired. Currently two variants exist: Puncture Cube or Access Cube, both Class 1 exempt, product code GDF. The Navigation Cubes support the use of needle sizes 10-20G (Access Cube) or 18-22G (Puncture Cube). Needle length is dependent on the trajectory, and can be derived from the displayed needle depth. Cube Navigator detects which Navigation Cube is present in the scan and then takes the average of the supported needle diameters for that Navigation Cube when calculating the thickness of the virtual needle.

Cube Navigator is a standalone software that integrates with the CE-marked and FDA-cleared diagnostic Medical Imaging Viewer medDream manufactured by Softneta (Class II, K222320, see Software Architecture Design Cube Navigator for integrated version). Cube Navigator allows the user to access the functionality of medDream by loading images locally or through a remote DICOM-connection, by viewing and manipulating DICOM-images through the user interfaces of the Cube Navigator, as well as accessing the functionality of Cube Navigator itself. The DICOM integration is part of the base software package medDream (see the Statement regarding the DICOM-Standard - Cube Navigator for detailed information about DICOM conformity).

Cube Navigator as well as the Navigation Cubes are manufactured and distributed by Medical Templates AG. medDream is manufactured by Softneta and for the described purpose, distributed by Medical Templates AG as bundle together with Cube Navigator. When the user installs Cube Navigator, medDream is also installed, without any additional installation or configuration necessary.

Customer support for Cube Navigator is provided by Medical Templates AG. This includes support for medDream functions accessible through Cube Navigator. Maintenance is provided by Medical Templates AG in the form of regular updates and/or patches. These updates and patches may include updates to medDream if necessary updates for medDream are available. A link to updates or patches, along with instructions on how to install them, will be distributed via email to the user.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Cube Navigator is a non-invasive software intended for planning the needle trajectory of CT-guided, percutaneous punctures using DICOM-images and a Navigation Cube attached to a patient. It is indicated for the planning the needle trajectory of CT-guided, percutaneous punctures for therapeutic and diagnostic purposes. The software's functionality allows to automatically recognize orientation, position and type of the Navigation Cube present in the DICOM-images and to manually define virtual needle trajectories to a physician-identified target through the Navigation Cube. Based on this planning, Cube Navigator provides physician information for such purpose.

Cube Navigator can only be used in combination with a Navigation Cube, specifically, either the Access Cube for instruments 10-20G (article number mt-ac-ct-20, Class 1 exempt, product code GDF) or the Puncture Cube for instruments 18-22G (article number mt-pc-ct-25, Class 1 exempt, product code GDF). Cube Navigator is a standalone software that integrates the CE-marked and FDA-cleared diagnostic Medical Imaging Viewer medDream manufactured by Softneta that provides all DICOM-related functionality like displaying and manipulating DICOM-images.

The Cube Navigator is intended for interventional radiologists, who perform CT-guided interventions for therapeutic and diagnostic purposes. The intended use environment is the CT control room, which can be in a hospital or a medical office.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Cube Navigator has substantially equivalent Intended Use as the predicate device, in that it is a software application that allows the user to define a virtual needle path in the displayed DICOM-images and provides information to the user for treatment planning. In comparison to the Indications For Use of the predicate device, which provides functionality for the planning of needle paths as one of many functions, the Cube Navigator software is limited to be used for such planning of needle paths as described in the Indication for Use Statement. The differences in the Indications for use stem from that limitation. Therefor the difference in the Indications for Use do not affect the safety and effectiveness of the device when used as labeled.

Cube Navigator is a non-invasive software intended for planning the needle trajectory of CT-guided, percutaneous punctures using DICOM-images and a Navigation Cube attached to a patient. It is indicated for the planning the needle trajectory of CT-guided, percutaneous punctures for therapeutic and diagnostic purposes. The software's functionality allows to automatically recognize orientation, position and type of the Navigation Cube present in the DICOM-images and to manually define virtual needle trajectories to a physician-identified target through the Navigation Cube. Based on this planning, Cube Navigator provides physician information for such purpose.

Cube Navigator can only be used in combination with a Navigation Cube, specifically, either the Access Cube for instruments 10-20G (article number mt-ac-ct-20, Class 1 exempt, product code GDF) or the Puncture Cube for instruments 18-22G (article number mt-pc-ct-25, Class 1 exempt, product code GDF). Cube Navigator is a standalone software that integrates the CE-marked and FDA-cleared diagnostic Medical Imaging Viewer medDream manufactured by Softneta that provides all DICOM-related functionality like displaying and manipulating DICOM-images.

The Cube Navigator is intended for interventional radiologists, who perform CT-guided interventions for therapeutic and diagnostic purposes. The intended use environment is the CT control room, which can be in a hospital or a medical office.

Technological Comparison

21 CFR 807.92(a)(6)

Cube Navigator software and the predicate device, are both software tools that enable the user to plan a virtual needle path in the displayed DICOM-images. While the predicate is an image analysis software application for reviewing body imaging studies that also provides functionality for that purpose, the Cube Navigator provides only functionality for that purpose. To achieve this it integrates the existing DICOM-Viewer MedDream (Class II, K222320, manufactured by Softneta UAB) on which the planning functionality is based. In comparison to the predicate device functionality of the Cube Navigator is limited to the features relevant for the planning. Therefor this difference in features does not raise different questions of safety and effectiveness. As those features of the predicate device not present in the Cube Navigator are possibly associated with risks regarding safety and effectiveness, this difference in features rather leaves the Cube Navigator associated with less risks overall in comparison to the predicate device.
Another difference in functional features is that the Cube Navigator provides information based on the registration and the user's defined needle path, that helps the user understand through which holes of the Navigation Cube the virtual needle is currently going and what the corresponding virtual needle depth is. The information provided is based on the registration performed as a first step in the process of planning and the user's input to define the position of the virtual needle. In principle risks may arise from a faulty

registration, which is a risk that is also relevant for the automated registration for viewing and analyzing multiphase or multiple time-point volume datasets, a feature provided by the predicate device. Another source of potential risk is the virtual needle path planning, that is also a feature in the predicate device. Using the predicate device the user need to manually determine through which holes of the Navigation Cube the current virtual needle path is leading and what the needle depth is. The Cube Navigator provides this information for the user and therefor simplifies this process thereby erasing potential source of error due to human error. Therefor this difference in features does not raise different questions of safety and effectiveness. Cube Navigator has the same intended use as the predicate device and is substantially equivalent in performance. Any technological differences do not raise any new potential safety risk. In conclusion the Cube Navigator software is substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Verification of automated registration accuracy:Data from phantom studies and retrospectively collected patient cases are used to determine the accuracy of the registration tool to automatically detect and register Navigation Cubes. Verification of displayed needle depth:In order to verify the needle length indicated in the sidebar a dataset is loaded, the cube is registered and the needle trajectory is planned. The calculated needle-depth is verified by measuring the distance from the tip of the needle to the corresponding plate in the cube with the line measurement tool provided by MedDream (FDA certified product). By comparing the two values to each other the error of the indicated needle length is determined .Side by side comparison of mechanism to interactively define virtual needle path for planningThe needle planning capability of the software end-to-end is verified by scanning an existing puncture, registering the cube, planning the virtual needle in the same trajectory as the physical one and comparing if the suggested coordinates for the needle plan by the software are equal to the actual coordinates used for the physical needle. This provides the advantage that it can be done retrospectively on existing data and excludes effects not related to the performance of the software such as actual puncturing by the clinician. For each cube 5 datasets from different tests or studies have been selected and the above conducted process has shown that for all cases the needle coordinates suggested by the software coincide with the actual coordinates for the needle in the physical setup. It is worth mentioning that apart from suggesting the correct coordinates for the needle plan (holes and corners) the accuracy of the physical puncture is mostly related to the physical design of the cube and its coordinate grids (holes and corners). With regards to needle diameter an average needle gauge of 0.9 mm for Puncture Cube and 1.2 mm for Access Cube is used in the software as simulations have shown that accuracy only varies slightly for the different needle diameters.Usability Study:A usability study was conducted where 5 interventional radiologists from independent sites used the software to plan a intervention successfully and provided feedback along the line of the intended use of the system. It was shown that the Cube Navigator is safe and effective to use.

No clinical tests have been submitted, referenced. or relied on in the premarket notification submission for a determination of substantial equivalence.

Based on the non-clinical test conducted we find Cube Navigator to be as safe, as effective and performs as well as the predicate device.