January 20, 2023

Tornier SAS
Moyees Kamara
Staff Specialist, Regulatory Affairs
161 rue LAVOISIER
Montbonnot Saint Martin, 38330
France

Re: K222510
Trade/Device Name: Blueprint Mixed Reality system
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, LLZ
Dated: December 20, 2022
Received: December 21, 2022

Dear Moyees Kamara:

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222510

Device Name
Blueprint® Mixed Reality system

Indications for Use *(Describe)*
Blueprint® Mixed Reality system is indicated for use during Total Shoulder Arthroplasty using Stryker's FDA cleared implants that are also implants cleared for pre-operative planning with the Blueprint® Software. Blueprint® Mixed Reality system is intended to allow surgeons to visualize the Blueprint® 3D preoperative planning intra-operatively. Blueprint® Mixed Reality system is also indicated for stereotaxic surgery to guide the placement of a glenoid pin provided that registration between the patient's anatomical landmarks / surfaces can be established on the preoperative CT based plan. Blueprint® Mixed Reality system is to be only used for skeletally matured adult patients.

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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K222510

Date Prepared: August 17, 2022

Administrative Information

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Title:	Staff Specialist, Regulatory Affairs
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Device Information

Name of Device:	Blueprint® Mixed Reality system
Common Name (s):	Orthopedic Stereotaxic Instrument
Regulatory Class:	II
Regulation:	21 CFR 882.4560, Stereotaxic instrument
Product Codes:	OLO, LLZ

Predicate Device Information

Predicate:	ExactechGPS® Total Shoulder Application (K173372)
Reference Device:	Tornier Perform™ Patient-Matched Primary Reversed Glenoid and BLUEPRINT™ Patient Specific Instrumentation (K211359)

Device Description

The Blueprint® Mixed Reality system is used to intraoperatively display stereoscopic three-dimensional images of the Blueprint shoulder arthroplasty preoperative plan and to guide and enable the insertion of a pin following the reaming axis aimed at preparing the glenoid fossa surface to facilitate the placement of the implant. The Blueprint Mixed Reality system allows the user to both see the patient in real-time and their internal boney anatomy displayed on see-through screens of a head-mounted device (goggles).

The Blueprint Mixed Reality system assists surgeons in visualizing stereoscopic three-dimensional images of the patient's boney anatomy and intraoperatively aid by guiding the pin during placement through real-time feedback.

The Blueprint Mixed Reality system is composed of three main components including the HOLOBLUEPRINT software, Microsoft® HoloLens 2 Goggles, and Instrumentation.

The Blueprint Mixed Reality system runs the HOLOBLUEPRINT software application on the Microsoft HoloLens 2 using Microsoft Windows Holographic Operating System. The Blueprint Mixed Reality system leverages the reference device by receiving planned glenoid cases as input for visualizing and guiding the placement of the pin during the shoulder arthroplasty procedure. The digital components of the system interface with specialized surgical instrumentation to enable intra-operative guidance through real-time feedback to the surgeon.

The components of the subject device are as follows:

HOLOBLUEPRINT™ Software

- HOLOBLUEPRINT is designed and written by Tornier SAS specifically for use on the Microsoft HoloLens 2 goggles (hardware). The HOLOBLUEPRINT software is to be installed on the hardware to be used by the surgeon as part of the Blueprint Mixed Reality system.

HoloLens 2 goggles (HoloLens 2)

- The HoloLens 2 is a Microsoft hardware that runs Microsoft Windows 10 Holographic Operating System. HoloLens 2 is a see-through, mixed reality head-mounted smart glasses.

Instrumentations (Instruments)

There are four reusable instruments and one single-use (sterile) instrument designed specifically for use with the Blueprint Mixed Reality system (subject device). The subject device system instruments include a Glenoid Pin Guide, Glenoid Digitizer, Instruments Check Block, Coracoid Clamp, and a Depth Stop Pin (Sterile).

The subject device is compatible with all Tornier (Stryker) commercially FDA-cleared glenoid implants (Except Patient Matched Implants) available in the reference device (K211359). The compatibility of implants with the reference device was validated and verification was performed for glenoid guidance and visualization of the patient's boney anatomy.

Indications for Use

Blueprint® Mixed Reality system is indicated for use during Total Shoulder Arthroplasty using Stryker's FDA cleared implants that are also implants cleared for pre-operative planning with the Blueprint® Software. Blueprint® Mixed Reality system is intended to allow surgeons to visualize the Blueprint® 3D preoperative planning intra-operatively. Blueprint® Mixed Reality system is also indicated for stereotaxic surgery to guide the placement of a glenoid pin provided that registration between the patient's anatomical landmarks / surfaces can be established on the preoperative CT based plan. Blueprint® Mixed Reality system is to be only used for skeletally matured adult patients.

Contraindications

- Blueprint Mixed Reality system is not to be used for non-adult patients.
- Blueprint Mixed Reality system is not to be used for diagnostic purposes.
- Blueprint Mixed Reality system is not to be used with a range of implants other than commercially authorized and Mixed Reality compatible Stryker/Tornier implants.
- Blueprint Mixed Reality system is not to be used by surgeons with a history of seizures or epilepsy
- Blueprint Mixed Reality system is not to be used by surgeons with vision issues that will not allow them to visualize the 3D interface clearly and comfortably.
- Blueprint Mixed Reality system is unsuitable to be used on patients with insufficient coracoid bone stock which limits coracoid instrument fixation

Technological Characteristics Comparison to Predicate Device

The subject device, Blueprint Mixed Reality system, and the predicate device, ExactechGPS (K173372) share similar technological characteristics as follows:

- Intended Use and Indications for Use
- Principles of operations
- Target population and user
- General technological features
- Intraoperative use
- Main system components
- Surgical instruments for navigation with markers
- Device accuracy requirements
- Environmental use
- Surgical Workflow and tracking system technology

The differences between the subject device, subject device, and predicate device include:

- The camera positioning is a near-eye, head-mounted device (HoloLens 2) instead of a screen on a desktop monitor, mounted on a platform systems cart to display information to the surgeon.
- The use of an active sensor versus passive sensors
- The tracking system technology is RGB instead of visible images

The Technological differences between the subject and predicate software devices are supported with verification and validation evaluations. The operating principle of the subject device is the same as that of the predicate device.

The differences in technological characteristics do not raise new questions of safety and effectiveness over the predicate device as demonstrated in validation and verification testing performed.

Substantial Equivalence - Non-clinical Performance Evidence

Non-clinical testing was performed to demonstrate substantial equivalence to the predicate device. They include:

- Bench Testing – conducted to demonstrate the HOLOBLUEPRINT™ software performs as per the systems requirements and specifications. The accuracy and repeatability were tested.
- System Accuracy Validation – The system was validated through cadaver testing to determine its accuracy to establish the performance equivalency of the predicate device.
- Functional and Performance Testing – the subject device was tested as required by IEC 62304 standards and FDA Guidance document *General Principles of Software Validation* issued on January 11, 2002. The goal of the tests was as follows:
    - Software Verification – testing was performed to ensure all design outputs meet specified requirements. The software for the subject device was considered a "moderate" level of concern as per the FDA guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (issued on May 11, 2005).
    - User needs Validation – performed to ensure software specifications conform to user needs and intended uses. The system was validated through cadaver and simulated use cases as per IEC 62366-1 standard. All requirements were met, and no new question of safety and effectiveness was raised.
    - Systems Instruments – testing was performed to confirm that all instruments

satisfy functional and performance requirements.

- Biocompatibility, Cleaning, Sterilization, Packaging, and Shelf life for the subject device instruments were assessed in accordance with recognized consensus standards.

The subject device components were also assessed in accordance with recognized consensus standards. All tests were successfully completed and passed.

Substantial Equivalence - Clinical Evidence

Clinical testing was not deemed necessary for the determination of substantial equivalence.

Substantial Equivalence - Conclusions

The Blueprint Mixed Reality system (subject device) does not raise new questions of safety or effectiveness. Differences in technological characteristics have been addressed with performance testing. The results of performance testing for the subject device support substantial equivalence to the predicate device, ExactechGPS (K173372, cleared November 24, 2017).