January 28, 2021

Surgical Planning Associates, Inc
% Kellen Hills
Quality and Regulatory Consultant
Orchid Design
80 Shelton Technology Center
Shelton, Connecticut 06484

Re: K200384
Trade/Device Name: HipXpert System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OSF, OLO
Dated: December 23, 2020
Received: December 29, 2020

Dear Kellen Hills:

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; 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200384

Device Name
HipXpert System

Indications for Use *(Describe)*
The HipXpert system is a manual surgical instrument and associated software application designed for use in planning surgery and aligning the acetabular components during hip arthroplasty procedures.

The HipXpert 3D Display and Anchoring application with the HoloLens2 is indicated for visual alignment of an acetabular cup impactor during hip arthroplasty when pin-based fixation of the HipXpert tool is utilized.

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.

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510(k) Summary

[As Required by 21 CFR 807.92]

(a)(1)	Date Prepared:	December 23, 2020
	Submitted By:	Surgical Planning Associates, Inc. New England Baptist Hospital, 125 Parker Hill Ave Suite 545 Boston, MA 02120
	Phone:	617-277-4434
	Contact:	Stephen B Murphy, M.D.
	Prepared By:	Orchid Design 80 Shelton Technology Center, Shelton, CT 06484
	Phone:	(203) 922 0105
(a)(2)	Proprietary Name:	HipXpert System
	Common Name:	Patient specific manual orthopedic stereotaxic system
	Classification Name and Reference:	21CFR 882.4560 - Stereotaxic instrument
	Product Codes:	OSF - Patient Specific Manual Orthopedic Stereotaxic System OLO - Orthopedic Stereotaxic Instrument
(a)(3)	Predicate Devices:	
	Primary:	Surgical Planning Associates, Inc - Hip Sextant Instrument System (K093491)
	Reference:	Augmedics, Ltd - xvision Spine (K190929)

(a)(4) Device Description:

The HipXpert system provides a patient-specific hip arthroplasty surgical plan allowing for accurate acetabular positioning using CT mapping of a patient's pelvis using a software application and a reusable, manual, mechanical navigation instrument.

The HipXpert software planning application uses patient image data to create a detailed 3D model of the pelvis as well as the instrument settings necessary for proper acetabular cup orientation.

The HipXpert mechanical instrument has three legs which are secured to the pelvis. The legs form three points which define the sextant plane. The HipXpert mechanical instrument has two protractors that are adjusted to orientate an indicator pin in the direction of the desired orientation of the acetabular component.

The purpose of this submission is to introduce a variant of the device that was cleared in K093491 which uses a different software application to allow the user to see the existing 3D objects provided in the surgery plans in three-dimensions on mixed reality lenses. Additionally, the indications for use have been amended to add clarity and align with the "Physical State" as specified by product code OSF.

The subject HipXpert 3D Display and Anchoring Application utilizes the previously cleared (K093491) HipXpert planning application and HipXpert tools in addition to a mixed reality headset (Microsoft HoloLens2) and QR target. The HoloLens2 is an off-the-shelf component developed and manufactured by Microsoft which is used to view superimposed 3D images from the HipXpert planning application on the real HipXpert tool. In order to properly orient the 3D images displayed by the HoloLens2, a QR target is used to anchor these 3D images in space as they are overlaid on the real HipXpert tool.

(a)(5) Indications for Use:

The HipXpert system is a manual surgical instrument and associated software application designed for use in planning surgery and aligning the acetabular components during hip arthroplasty procedures.

The HipXpert 3D Display and Anchoring application with the HoloLens2 is indicated for visual alignment of an acetabular cup impactor during hip arthroplasty when pin-based fixation of the HipXpert tool is utilized.

(a)(6) Comparison of Technological Characteristics:

The HipXpert system is substantially equivalent to the previously cleared hip sextant system based on similarities in intended use, design, materials, packaging, sterilization and performance. The only difference is an additional software application which allows the user to view existing 3D objects provided in the surgery plans in three-dimensions using mixed reality lenses. The use of a headset for presenting stereoscopic augmented reality (AR) display of patient's anatomy is not a new feature and has been previously cleared under K190929 for the xvision Spine (reference device). The technological characteristics do not raise any new questions of safety and efficacy.

(b)(1) Non-clinical testing:

The subject device modification was successfully evaluated according to the following:

- Validation of the software used for file identification, QR target recognition and file anchoring
- Verification of overall system orientation and position accuracy in a cadaveric model using screws placed into the acetabulum

- Verification of system accuracy, image registration accuracy and tracking accuracy using methods analogous to ASTM F2554-10 under varying conditions of light, motion, distance, and angle
- Performance of the Headset display was demonstrated by verifying the following elements: Field of View (FOV), resolution, luminance, distortion, contrast ratio, contrast of physical object, location of the virtual image, and stability of the virtual objects due to motion

(b)(2) Clinical testing:
Clinical testing was not required to demonstrate substantial equivalence in this premarket notification.

(b)(3) Conclusions:
Based on the information provided in this premarket notification, we believe that the subject HipXpert system demonstrates substantial equivalence to the predicate Hip Sextant Instrument System.