August 8, 2024

Surgical Planning Associates, Inc
% Kellen Hills
Biomedical Engineer
Hills Quality and Regulatory Services, LLC
8971 Oakwood Lane
Olive Branch, Mississippi 38654

Re: K233315
Trade/Device Name: HipXpert and HipInsight System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OSF, SBF
Dated: May 10, 2024
Received: May 10, 2024

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 (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,

Tejen D. Soni -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233315

Device Name

HipXpert and HipInsight Systems

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 HipInsight system with the HoloLens2 is indicated for visualization of the HipXpert surgical plan and alignment of acetabular implants and instrumentation during hip arthroplasty when pin-based fixation of the HipXpert tools 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K233315

510(k) Summary

Prepared on: 2024-08-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Surgical Planning Associates, Inc
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	HipXpert and HipInsight Systems
Common Name	Stereotaxic instrument
Classification Name	Patient Specific Manual Orthopedic Stereotaxic System
Regulation Number	882.4560
Product Code(s)	OSF, SBF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200384	HipXpert System	OSF

Device Description Summary

21 CFR 807.92(a)(4)

The HipInsight System was cleared in K200384 and utilizes the Microsoft HoloLens2 mixed reality headset to display 3D images from the HipXpert planning application. The 3D images are superimposed on the actual patient using known anchoring landmarks relative to the anterior pelvic plane.

The HipXpert software planning application uses CT 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 planning application has the ability to show implant and instrument templates that are either generic or manufacturer specific. The templates can be positioned in relation to the patient's pelvis and femur bones in the surgical plan.

The surgical plan, including all tool settings and usage instructions, is posted to the surgeon's secure folder on the HipXpert website.

The operating surgeon can then download the plan to a desktop or laptop computer and use the HipXpert viewer application to view and adjust the plan according to his/her best surgical judgment.

The purpose of this submission is to introduce additional options for the HipInsight system.

Additional surgeon needs include being able to:
- Use mixed-reality guidance with additional 3D objects
- Use mixed-reality guidance without using the HipXpert mechanical docking tools
- Use mixed-reality guidance that provides position accuracy in addition to orientation accuracy
- Use mixed-reality guidance for limb length measurements

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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 HipInsight system with the HoloLens2 is indicated for visualization of the HipXpert surgical plan and alignment of acetabular implants and instrumentation during hip arthroplasty when pin-based fixation of the HipXpert tools is utilized.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications were amended to address the additional 3D objects being displayed by the HipInsight system. The software allows for additional 3D objects to be aligned using the HoloLens2, including instruments and implants. The indications were also amended to clarify that the "HipXpert surgical plan" would also be included in the display of the HipInsight system, which has always been the case. All 3D objects would be oriented relative to the anterior pelvic plane as defined during the HipXpert planning process. There is no change to the intended users, patient population, or surgical intervention.
There are no significant differences between the subject and predicate devices that would raise new questions of safety or effectiveness. The FDA classification is identical between the devices as is the intended use, despite slight differences in the exact verbiage of the indications for use.

Technological Comparison

21 CFR 807.92(a)(6)

The HipInsight system uses software and the Microsoft HoloLens2 to display 3D models generated by the HipXpert Planning application. The proposed updates to the HipXpert and HipInsight systems will allow for orientation alignment and positional placement of additional 3D objects including instruments and implants without the requirement to use the physical HipXpert mechanical tool.

The performance testing methodology utilized in K200384 is also utilized to evaluate the proposed software updates. All results in terms of orientation and position accuracy of the subject device were equivalent to those of the predicate.

There are no significant differences between the subject and predicate devices that would raise new questions of safety or effectiveness. The subject and predicate devices utilize identical materials, design, sterility, and packaging. The software modifications provide additional options to the surgeon.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Simulated cadaveric specimens were used to evaluate the accuracy of the design changes described in this 510(k). All results in terms of orientation and position accuracy of the subject device were equivalent to those of the predicate.

No clinical testing was conducted to support the determination of substantial equivalence.

Based on the information provided in this premarket notification, we believe that the subject HipXpert/HipInsight systems demonstrate substantial equivalence to the predicate.