Stryker Corp.
Cara Mellits
Sr. Regulatory Affairs Specialist
5900 Optical Ct
SAN JOSE, CA 95138

December 13, 2018

Re: K182359
Trade/Device Name: HipCheck
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 12, 2018
Received: November 14, 2018

Dear Cara Mellits:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182359

Device Name
HipCheck

Indications for Use *(Describe)*

HipCheck provides static localization information derived from image processing of intra-operatively acquired X-ray images, by superposition of virtual measurement tools onto those X-ray images.

HipCheck assists the surgeon to determine quantitative measurements during femoroacetabular impingement procedures.

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

I. SUBMITTER

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Contact Person: Cara Mellits

Date Prepared: August 28, 2018

II. DEVICE

Name of Device: HipCheck
Common or Usual Name: HipCheck
Classification Name: Picture Archiving and Communications System (21 CFR 892.2050)
Regulatory Class: II
Product Code: LLZ

III. PREDICATE DEVICES

Primary Predicate:

Dyonics Plan Hip Impingement Planning Software, K132636

Secondary Predicate:

FluoroMap Computer Assisted Surgery System, K103400

Neither predicate has been subject to a design-related recall.

IV. DEVICE DESCRIPTION

HipCheck enables the surgeon to intraoperatively measure alpha angle during hip arthroscopy procedures for femoroacetabular impingement. The software is provided to the user pre-installed on a mobile touchscreen tablet for which it has been tested for compatibility.

Alpha angle is a value used to indicate cam deformity of the femoral head, seen in patients presenting with femoroacetabular impingement. HipCheck provides a visualization tool for surgeons to determine the alpha angle intraoperatively, using virtual measurement tools superimposed on X-ray images collected during the procedure, which informs clinical decision making.

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510(k) Summary

HipCheck is not patient contacting. The user is instructed to appropriately drape the tablet when used in the sterile field.

The femoral head detection algorithm on which the alpha angle algorithm is built, is based on the Femoral Head Detector algorithm used in the FluoroMap 1.0 software, which belongs to the secondary predicate device, the FluoroMap Computer Assisted Surgery System (K103400).

V. INTENDED USE

HipCheck provides static localization information derived from image processing of intra-operatively acquired X-ray images, by superposition of virtual measurement tools onto those X-ray images.

VI. INDICATIONS FOR USE

HipCheck assists the surgeon to determine quantitative measurements during femoroacetabular impingement procedures.

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510(k) Summary

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Characteristic	**Subject Device** *HipCheck*	**Primary Predicate Device** *Dyonics Plan Hip Impingement Planning Software*	**Secondary Predicate Device** *FluoroMap Computer Assisted Surgery System*
Intended Use	HipCheck provides static localization information derived from image processing of intra-operatively acquired X-ray images, by superposition of virtual measurement tools onto those X-ray images.	The DYONICS PLAN is intended as pre-operative or post-operative software for simulating/evaluating hip preservation surgical treatment options and historical case review, respectively.	FluoroMap is a computer controlled stereotaxic image guided surgery system. It provides static localization information derived from image processing of intra-operatively acquired X-ray images, by superposition of virtual implants and instruments onto those X-ray images.
Indications for Use Statement	HipCheck assists the surgeon to determine quantitative measurements during femoroacetabular impingement procedures.	The DYONICS PLAN Hip Impingement Planning System software is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner to an output file. It is also intended as pre-operative or post-operative software for simulating/evaluating hip preservation surgical treatment options and historical case review, respectively.	FluoroMap assists the surgeon to determine the needed size and position of orthopedic implants during proximal femur fracture surgery using the Stryker Gamma3 Nail system. The system should be operated only by trained personnel such as surgeons and clinical staff.
Product Code(s)	Same as predicate.	LLZ	OLO, LLZ
Regulation Number	Same as predicate.	892.2050	882.4560

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510(k) Summary

Intended Patient Population	Same as predicate.	Patients undergoing orthopedic surgery.	Patients undergoing orthopedic surgery.
Surgical Approach	Orthopedic surgery, specifically femoroacetabular impingement.	Orthopedic surgery, specifically hip preservation treatment options.	Orthopedic surgery, specifically at the proximal femur.
Intended Users	Same as predicate.	Orthopedic surgeons and other healthcare professionals.	Surgeons and clinical staff.
Operational Environment	Surgical suite. Postoperative case review.	Preoperative planning. Postoperative case review.	Surgical suite.
Primary Device Function	Locate the femoral head and neck to determine the alpha angle using intra-operative X-ray images.	Visualization and assessment of hip preservation surgical treatment options using CT images.	Assistance in planning and positioning of orthopedic implants using intra-operative X-ray images.
Main System Components	Same as predicate.	- Software	- Software - Reference device for C-arm - Reference device for instrumentation
User Interface	Tablet.	Personal Computer (PC).	Computer and monitor.
Body Contact and Use	Same as predicate.	N/A – Device does not have any patient contact.	Reference device for instrumentation (closed tube clip) has patient contact.
Sterile, Single-use	Same as predicate.	N/A – Device is not provided sterile or as a single use product.	Reference device for instrumentation (closed tube clip) is delivered sterile and as a single use product.
Design	- Workstation for viewing software - Dedicated software for image processing and display of virtual measurement tools	- Installed and run locally on a PC - Software for image processing - Provides virtual measurement tools, surgical simulation and planning tools	- Reference frames containing metal marker spheres - Reference frames are attached to the implant system and to the C-arm - Workstation for viewing software - Dedicated software for image processing and display of positional information
Principles of Operation	Acquire intra-operative X-ray images, process the images and	Stand-alone software for computer assisted surgical planning, via	Acquire intra-operative X-ray images, register the images through metal

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510(k) Summary

	display the virtual measurement tools onto images.	import of CT scans in DICOM format, provides image processing and measurement tools.	marker detection and display the actual position of instruments and implants onto images.
Function	Display on a tablet screen virtual measurement tools in relationship to X-ray images.	Display on a computer screen virtual measurement and surgical planning tools in relationship to 2D views and 3D renderings generated from CT scans.	Display on a computer screen navigated instruments and implants in relationship to X-ray images.
Image Processing	- Transfer X-ray images from C-arm to computer platform - Overlay virtual measurement tools onto images	- Import DICOM images from CT scans to computer platform. - Process images to display various 2D views and 3D renderings. - Provide virtual measurement tools, surgical simulation and planning tools.	- Transfer X-ray images from C-arm to computer platform - Remove image distortions - Register images to patient space - Overlay instruments and implants onto images
Energy Source	Same as predicate.	No energy applied to the patient or operating staff.	No energy applied to the patient or operating staff.

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510(k) Summary

Discussion of Similarities and Differences

Primary Predicate (Dyonics Plan, K132636): Dyonics Plan is a surgical planning tool, in that its operational environment is primarily pre-operative, thereby outside the surgical suite. However, the software allows for the export of the plan in PDF or HTML format, which can be referenced intraoperatively. As such, the Dyonics Plan utilizes CT preoperative imaging for displaying 2D views and 3D renderings and provides virtual measurement tools for visualization and analysis of hip preservation treatment options. HipCheck's operational environment is primarily intraoperative, within the surgical suite. Since HipCheck is primarily used intraoperatively, it displays intraoperatively collected X-ray images, likewise providing virtual measurement tools for visualization purposes during femoroacetabular impingement procedures.

While the operational environment may differ, the intended use is the same. Dyonics Plan utilizes image processing of preoperative CT images and virtual measurement tools to visualize hip anatomy and plan preservation procedures. HipCheck utilizes image processing of intraoperatively collected X-ray images and virtual measurement tools to visualize hip anatomy during femoroacetabular impingement procedures. The Dyonics Plan and HipCheck have the same intended use, as defined in their shared regulation 21 CFR 892.2050. Though their indications for use statements differ, both are used in the treatment of femoroacetabular impingement.

Secondary Predicate (FluoroMap, K103400): In addition to its clearance as an orthopedic stereotaxic instrument (OLO; 21 CFR 882.4560), FluoroMap is also cleared as a picture archiving and communications system (LLZ; 21 CFR 892.2050). This is due to the core functionality of FluoroMap's software that supports the acceptance, display, and digital processing of X-ray images in order for FluoroMap to function as intended. FluoroMap software facilitates image manipulation and quantification in order to achieve visualization of the placement of virtual implants and instruments.

Similarly, HipCheck shares this core functionality to achieve visualization of the placement of virtual measurement tools for the determination of alpha angle. HipCheck's Alpha Angle algorithm is built directly on the Femoral Head Detector algorithm within the FluoroMap software (K103400). HipCheck leverages the Femoral Head Detector algorithm from FluoroMap for its same intended purpose, simply in a different application.

While the primary function of FluoroMap is as a navigated surgical system for placing orthopedic implants, the *how* behind the device's ability to achieve its intended purpose is important in the substantial equivalence discussion for HipCheck.

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510(k) Summary

VIII. PERFRMANCE DATA/NON-CLINICAL TESTING

Design verification testing was performed on HipCheck as a result of the risk analysis and product requirements. Testing included software and bench verification testing, as well as design validation. Design validation testing was conducted in a simulated-use environment by surgeon and nurse users. Users were successfully able to use the HipCheck as intended to determine the alpha angle and utilize the virtual measurement and visualization tools.

Software testing

Software testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered to be of "moderate" level of concern since a failure or latent flaw in the software could indirectly result in minor injury to the patient or operator.

Alpha Angle Performance Testing

Alpha angle performance was evaluated in both verification and validation testing performed for HipCheck. Verification testing was conducted based on the identified design requirements and software requirement specifications of the Alpha Angle Core Algorithm. Additionally, validation testing was conducted to ensure applicable user needs were met for generating, manipulating, and using the overlay to determine the alpha angle. All testing had overall passing results.

Mechanical testing

Mechanical functionality testing included the following to ensure the device design meets user needs in the environment of use:

- Battery life
- Tablet weight
- Tablet securement and attachment force to evaluate the connection between the tablet and its docking interface on the compatible operating table mounting arm
- User interface temperature and functionality at operating temperatures
- RF ablation interference
- Mounting arm staying force
- Simulated-use testing

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing was conducted on the compatible touchscreen tablet that the HipCheck software is provided pre-installed on. The tablet complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

Animal Study

No animal testing was conducted to determine the safety and effectiveness of HipCheck.

Clinical Studies

No human clinical testing was conducted to determine the safety and effectiveness of HipCheck.

IX. CONCLUSIONS

Based on the shared technological characteristics and intended use, HipCheck is substantially equivalent to the primary predicate, Dyonics Plan Hip Impingement Planning Software (K132636), and the secondary predicate, FluoroMap Computer Assisted Surgery System (K103400). Differences between the subject and predicate devices' technological characteristics do not raise different questions of safety and effectiveness of HipCheck. The results of the non-clinical testing conducted supports the safety of the device and demonstrates that HipCheck performs as intended in the specified use conditions.