Stryker Corp.
% Lucas Dan
Staff Regulatory Affairs Specialist
5900 Optical Ct
SAN JOSE CA 95138

September 29, 2023

Re: K230045
Trade/Device Name: HipCheck
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: August 21, 2023
Received: August 21, 2023

Dear Lucas Dan:

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).

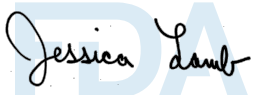
Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless 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,



Jessica Lamb, Ph.D.
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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)*
K230045

Device Name
HipCheck

Indications for Use *(Describe)*
HipCheck assists the surgeon to determine quantitative measurements for femoroacetabular impingement (FAI) procedures. HipCheck provides static localization information derived from image processing of intra-operatively acquired static fluoroscopic images, by superposition of virtual measurement tools onto those X-ray images for skeletally mature patients.

HipMap FAI Analysis is a patient-specific report used to support surgeon or radiologist pre-operative clinical decision making. HipMap femoroacetabular impingement (FAI) Analysis provides a morphological analysis of a skeletally mature hip with potential FAI, including measurements and visualizations that describe hip impingement and stability.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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510(k) Summary

I. SUBMITTER

Stryker Endoscopy
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Phone: 303-931-2353
Email: lucas.dan@stryker.com

Contact Person: Lucas Dan
Date Prepared: January 5th, 2023

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: QIH

III. PREDICATE DEVICE

HipCheck, K182359
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

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.

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

510(k) Summary

Stryker HipMap FAI Analysis is a patient-specific report intended for use by surgeons or radiologists to support pre-operative clinical decision making by providing a morphological analysis of a skeletally mature hip with potential femoroacetabular impingement (FAI), including measurements and visualizations that describe hip impingement and stability. HipMap provides three-dimensional analyses, 3D surface reconstructions, and annotated images to support surgeons with pre-operative clinical decision-making.

V. INTENDED USE/INDICATIONS FOR USE STATEMENT

HipCheck assists the surgeon to determine quantitative measurements for femoroacetabular impingement (FAI) procedures. HipCheck provides static localization information derived from image processing of intra-operatively acquired static fluoroscopic images, by superposition of virtual measurement tools onto those X-ray images for skeletally mature patients.

HipMap FAI Analysis is a patient-specific report used to support surgeon or radiologist pre-operative clinical decision making. HipMap femoroacetabular impingement (FAI) Analysis provides a morphological analysis of a skeletally mature hip with potential FAI, including measurements and visualizations that describe hip impingement and stability.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Characteristic	**Subject Device** *HipCheck* [K230045]	**Predicate Device** *HipCheck* [K182359]
Intended Use/Indications for Use Statement	HipCheck assists the surgeon to determine quantitative measurements for femoroacetabular impingement (FAI) procedures. HipCheck provides static localization information derived from image processing of intra-operatively acquired static fluoroscopic images, by superposition of virtual measurement tools onto those X-ray images for skeletally mature patients. HipMap FAI Analysis is a patient-specific report used to support surgeon or radiologist pre-operative clinical decision making. HipMap femoroacetabular impingement (FAI) Analysis provides a morphological analysis of a skeletally mature hip with	HipCheck assists the surgeon to determine quantitative measurements during femoroacetabular impingement procedures. 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.

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	potential FAI, including measurements and visualizations that describe hip impingement and stability.	
Product Code(s)	QIH	LLZ
Intended Patient Population	Same as predicate.	Patients undergoing arthroscopic surgery.
Surgical Approach	Same as predicate.	Arthroscopic surgery, specifically femoroacetabular impingement.
Intended Users	Same as predicate.	Surgeons and clinical staff.
Operational Environment	Same as predicate.	Surgical suite.
Primary Device Function	**HipCheck:** Locate the femoral head and neck to determine the alpha angle using intra-operative X-ray images. **HipMap FAI Analysis:** Provide three-dimensional analyses, 3D surface reconstructions, and annotated images to support surgeons with pre-operative clinical decision-making.	Locate the femoral head and neck to determine the alpha angle using intra-operative X-ray images.
Main System Components	Same as predicate.	Software
User Interface	**HipCheck:** Tablet **HipMap FAI Analysis:** General purpose computing platform and/or HipCheck tablet.	Tablet.
Body Contact and Use	Same as predicate.	N/A – Device does not have any patient contact.
Sterile, Single-use	Same as predicate.	N/A – Device is not provided sterile or as a single use product.
Design	**HipCheck:** - Workstation for viewing software - Dedicated software for image processing and display of virtual measurement tools **HipMap FAI Analysis:** Interactive HTML report for viewing on general purpose computing platform and/or HipCheck tablet.	- Workstation for viewing software - Dedicated software for image processing and display of virtual measurement tools

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Principles of Operation	**HipCheck:** Acquire intra-operative X-ray images, process the images and display the virtual measurement tools onto images. **HipMap FAI Analysis:** Process CT scan to create patient specific report with three-dimensional analyses, 3D surface reconstructions, and annotated images.	Acquire intra-operative X-ray images, process the images and display the virtual measurement tools onto images.
Function	**HipCheck:** Display on a tablet screen virtual measurement tools in relationship to X-ray images. **HipMap FAI Analysis:** Display a patient-specific report on a general purpose computing platform and/or HipCheck tablet.	Display on a tablet screen virtual measurement tools in relationship to X-ray images.
Input Methods	**HipCheck:** - USB - Stryker eRequest Platform (also referred to as the HipMap Portal) **HipMap FAI Analysis:** - Stryker eRequest Platform (also referred to as the HipMap Portal)	- USB
Export Methods	**HipCheck:** - USB - Stryker Health Cloud **HipMap FAI Analysis:** - Stryker eRequest Platform (also referred to as the HipMap Portal)	- USB
Image Processing	**HipCheck:** - Transfer X-ray images from C-arm to computer platform - Overlay virtual measurement tools onto images **HipMap FAI Analysis:** - Generate three-dimensional analyses and 3D surface reconstructions from CT scan	- Transfer X-ray images from C-arm to computer platform - Overlay virtual measurement tools onto images

510(k) Summary

Femoral Head Detection Workflow	Same as predicate.	- Extraction of the region of interest - Extended Gabor filtering - Binary edge detection and classification - Circular Hough transformation - Feature point tracing - RANSAC circle matching - Target circle selection
Energy Source	Same as predicate.	No energy applied to the patient or operating staff.
Software Level of Concern	Same as predicate.	Moderate
Software Operating Environment	**HipCheck:** Programming language used is C/C++. The operating system is Windows 10. The hardware platform consists of a microprocessor-controlled system, based on a PC.	Programming language used is C/C++. The operating system is Windows 8.1. The hardware platform consists of a microprocessor-controlled system, based on a PC.
Compatible Hospital Equipment	Same as predicate.	Compatible to 2D C-arms.

Discussion of Similarities and Differences

HipCheck version 1.5.6 contains three primary changes which are the subject of this 510(k). The first is a connectivity feature (Wireless and Ethernet) on the HipCheck tablet which allows for the secure importation and exportation of case data. The second is the change in operating system the HipCheck software runs on; HipCheck 1.5.6 utilizes the Windows 10 operating system whereas the predicate utilizes Windows 8. The third change is the inclusion of HipMap FAI Analysis.

Both the subject device and the predicate device share the core functionality to achieve visualization of the placement of virtual measurement tools for the determination of alpha angle. Updating to HipCheck version 1.5.6's Alpha Angle algorithm has been done to enhance capabilities of the algorithm on uncommon image types (i.e., corner cases) while maintaining consistent capabilities on other image types.

In addition to these changes, bug fixes, administrator tool updates, new troubleshooting features, and graphical user interface updates were implemented with the upgrade to HipCheck version 1.5.6. Differences between the subject device and predicate device's intended use, indications for use, and technological characteristics were evaluated through performance testing.

VII. PERFORMANCE DATA/NON-CLINICAL TESTING

Design verification testing was performed on HipCheck due to 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 sales representative 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 provided, as recommended by FDA Guidance for Industry and Staff – *Content of Premarket Submissions for Device Software Functions* (June 2023). The software for this device was considered to be of Basic Documentation Level of concern since a failure or flaw of any device software function could not present a hazardous situation with a probable risk of death or serious injury either to a patient, user of the device, or others in the environment of use prior to the implementation of risk control measures.

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Mechanical testing

Mechanical functionality testing was leveraged from the predicate device, HipCheck (K182359), including 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.

HipCheck Design Testing

Design verification testing was performed on HipCheck due to the risk analysis and product requirements. Testing included bench verification and design validation testing. Design validation testing was conducted in a simulated-use environment by surgeon and sales representative users. Testing from the previously cleared HipCheck (K182359) was leveraged as appropriate. Users were successfully able to use the HipCheck as intended to determine the alpha angle and utilize the virtual measurement and visualization tools.

Standalone Performance Testing

Stryker conducted standalone performance testing on an object detection AI/ML model that is a part of the image processing pipeline. The test dataset consists of 745 fluoroscopic images. 184 images did not contain images of hips and were used to test false positive

detection. 561 images were taken of 81 hips. Geographically, the images come from 6 clinical sites in the United States, Netherlands, and Germany representative of the intended use population. Numerous subgroups were evaluated to demonstrate the generalizability of the device across the dataset. Images were collected during product development cadaver labs or from anonymized log files from patients undergoing surgery with the use of HipCheck. The images were labeled using software for labeling the femur with the precise location of femoral head and neck. All images were tagged by two people trained to use the software. Testing was done against the average value of the two taggers. The test dataset was independent of the data used during model training and stored in a different access-controlled location.

The results of the standalone performance testing demonstrate the AI/ML model:

- Automatically detects the presence or absence of a hip (90% Lower Bound of 97.5%)
- Finds the region of the image that contains the femur with high accuracy:
    - Head center X coordinate is within +3.3%/-3.5
    - Head center Y coordinate is within +3.8%/-4.8%
    - Neck Angle relative to vertical is within +13.63°/-15.35°

Additionally, the performance was also validated for the following subgroups:

- Image Quality
    - Average
    - Good
- Alpha Angle
    - Low (<47.7°)
    - Medium (47.7°-65.5°)
    - High (>65.5°)
- Neck Width (as a ratio to Head Diameter)
    - Low (<0.63)
    - Medium (0.63-0.73)
    - High (>0.73)
- Neck Length (as a ratio to Head Diameter)
    - Low (<0.386)
    - Medium (0.386-0.465)
    - High (>0.465)
- Hip Position
    - 30° Internal Rotation, 0° Flexion
    - 0° Rotation, 0° Flexion
    - 30° External Rotation, 0° Flexion
    - 0° Rotation, 50° Flexion
    - 40° External Rotation, 50° Flexion
    - 60° External Rotation, 50° Flexion
- Femoral Head Size (as a ratio to Image Size)
    - Low (<0.301)

- Medium (0.301-0.343)
- High (>0.343)

HipMap Performance Testing

Stryker conducted a segmentation accuracy and reliability study using HipMap workflow software. It reviews the performance of Stryker personnel segmenting pelvic CT scans using HipMap workflow software against trained third-party personnel performing image segmentation of the same scans using 510(k) cleared software. It also reviews the reliability of segmentation between Stryker personnel, and the reliability of the HipMap FAI Analysis by comparing clinical measurement outputs generated from the third-party segmentation (external rater vs internal rater), Stryker employee segmentations (inter-rater reliability), and iterations of segmentations performed by the same Stryker employee (intra-rater reliability).

VIII. CONCLUSIONS

Based on the shared technological characteristics and intended use, HipCheck version 1.5.6 is substantially equivalent to the predicate, HipCheck (K182359). 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.