DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 31, 2017

Biomet, Inc.
% Mr. Paul Hardy
Regulatory Affairs Senior Specialist
56 East Bell Drive
PO Box 587
WARSAW IN 46581

Re: K162559
Trade/Device Name: Move Forward 3D Motion Simulation Service
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 23, 2017
Received: February 24, 2017

Dear Mr. Hardy:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162559

Device Name
Move Forward 3D Motion Simulation Service

Indications for Use *(Describe)*
Zimmer Biomet's Move Forward 3D Motion Simulation Service is an online image analysis service indicated for skeletally mature individuals that enables clinicians to obtain 3D motion simulation reports based on CT or MR image data.

The service can be used by uploading either CT or MR image data of hip joints. The image data is processed by Zimmer Biomet to create 3D anatomy models. These 3D models are then used to perform 3D motion simulations of the hip joint. The report also provides several calculated intersection zones that may improve the simulated range of motion. Move Forward also calculates several morphological shape parameters for each of the 3D anatomy models.

The software generates an interactive report as output. Clinicians do not interact with the image analysis software directly. The image analysis software is only operated by Zimmer Biomet operators who have been specifically trained for this purpose. End users of the generated Move Forward reports are trained medical professionals, including radiologists and orthopedic surgeons.

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

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Move Forward 3D Motion Simulation Service 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor: Biomet, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact: Paul Hardy
Regulatory Affairs Senior Specialist
574-372-6799

Date: February 22, 2017

Subject Device: Trade Name: Move Forward 3D Motion Simulation Service
Common Name: Hip impingement image analysis system

Classification Name:
- LLZ– Picture Archive and Communications System (PACS) (21 CFR 892.2050)

Legally marketed devices to which substantial equivalence is claimed:
- Dyonics Plan Hip Impingement Planning Software manufacturered by Smith & Nephew (K132636)

Device Description
The Move Forward 3D Motion Simulation Service is an online image analysis service that enables clinicians to obtain 3D motion simulation reports based on CT or MR image data. This service consists of three modules: CGOnline, Arbiter, and Articulis.

During the segmentation process, 3D bone models of the pelvis and femur bones are created from the image data. Any required editing of the segmentation images are performed by Zimmer Biomet operators. These 3D bone models are then used to perform 3D motion simulations of the hip joint. The 3D motion simulations can be used to visualize rigid shapes such as bones that come into contact with one another, thus potentially limiting range of motion. The system includes several calculated intersection zones that each individually improve the simulated range of motion. The system also calculates several morphological shape parameters for each of the 3D bone models.

The software generates an interactive PDF report as output, which Zimmer Biomet delivers to clinicians on a per case basis through the CGOnline module. In particular, the report that is generated provides information to the clinicians associated with femoroacetabular impingement (FAI). Clinicians do not interact with the image analysis software directly. The Articulis and Arbiter modules are only operated by Zimmer Biomet operators who have been specifically trained for this purpose. End users of the generated Move Forward reports are trained medical professionals, including radiologists and orthopedic surgeons.

Indications for Use
Zimmer Biomet's Move Forward 3D Motion Simulation Service is an online image analysis service indicated for skeletally mature individuals that enables clinicians to obtain 3D motion simulation reports based on CT or MR image data.

The service can be used by uploading either CT or MR image data of hip joints. The image data is processed by Zimmer Biomet to create 3D anatomy models. These 3D models are then used to perform 3D motion simulations of the hip joint. The report also provides several calculated intersection zones that may improve the simulated range of motion. Move Forward also calculates several morphological shape parameters for each of the 3D anatomy models.

The software generates an interactive report as an output. Clinicians do not interact with the image analysis software directly. The image analysis software is only operated by Zimmer Biomet operators who have been specifically trained for this purpose. End users of the generated Move Forward reports are trained medical professionals, including radiologists and orthopedic surgeons.

Intended Use
The Move Forward 3D Motion Simulation Service is intended as pre-operative or post-operative software for simulating/evaluating hip preservation surgical treatment options and historical case review, respectively.

Summary of Technological Characteristics
The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Indications for Use:** 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.
- **Intended Use:** The Dyonics Plan is intended as a pre-operative or post-operative software for simulating/evaluating hip preservation surgical treatment options and historical case review respectively.
- **Design Features:** Stand-alone software packages that have the following features:

- Input files consist of DICOM files from CTs for Dyonics and CTs and MRIs for 3D Move Forward Simulation Service
- The proposed and predicate device both provide image processing tools including image segmentation and 3D rendering tools
- The proposed and predicate device both have tools for surgical simulation and planning
- The proposed device allows for the display of anatomical parameters which the predicate device also provides for anatomical parameters.
- The proposed and predicate device provide an output report which can be referenced pre-operatively, post-operatively, and inter-operatively
- The proposed and predicate device provide range of motion simulations

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
  - Software Verification and Validation activities demonstrate that the Move Forward 3D Motion Simulation Service does not raise any new issues of safety and effectiveness as compared to the predicate device.

Substantial Equivalence Conclusion

The differences between the proposed and predicate device do not introduce new types of safety and effectiveness questions. The Move Forward 3D Motion Simulation Service is substantially equivalent to the Dyonics Plan software and the intended uses are identical.