DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 3, 2016

JointPoint, Inc.
% Ms. Michelle McDonough
Senior Associate, Regulatory & Clinical Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street, NW, 12th Floor
WASHINGTON DC 20005

Re: K160284
Trade/Device Name: JointPoint
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, HAW
Dated: June 30, 2016
Received: July 5, 2016

Dear Ms. McDonough:

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)*
K160284

Device Name
JointPoint

Indications for Use *(Describe)*
JointPoint is an image-processing software indicated to assist in the positioning of total hip replacement components. It is intended to assist in precisely positioning total hip replacement components intra-operatively by measuring their positions relative to the bone structures of interest provided that the points of interest can be identified from radiology images.

JointPoint is also indicated for assisting healthcare professionals in preoperative planning and postoperative analysis of orthopedic surgery in Total Hip Replacement, Total Knee Replacement, and Intertrochanteric Fracture Reduction. The device allows for overlaying of prosthesis templates on radiological images, and includes tools for performing measurements on the image and for positioning the template. Clinical judgment and experience are required to properly use the software. The software is not for primary image interpretation. The software is not for use on mobile phones.

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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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

Manufacturer: JointPoint, Inc.
402 Buttonwood Lane
Largo, FL 33770

Contact: Michelle McDonough, MS
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street, NW, 12th Floor
Washington, DC 20005
202.552.5800 (phone)
202.552.5798 (fax)

Date Prepared: August 2, 2016

Device Trade Name: JointPoint

Common Name: Picture archiving and communications system (PACS)

Classification: 21 CFR 892.2050

Class: II

Product Code: LLZ; HAW

Indications For Use:
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Device Description:
JointPoint is a non-invasive software system intended to provide preoperative templating for orthopaedic procedures and intraoperative data for total hip arthroplasties (THA). The JointPoint software is a client/server based software product wherein a primary server software component and database store user, patient and case information and a client software package is installed on

user devices such as laptops or tablets. The two software components communicate with each other over the internet in a fully HIPAA compliant manner. The medical aspects of the software can function on the laptop or tablet alone, without the user of the internet, so that the system will still function in an OR that does not have internet connectivity.

Predicate Devices:
JointPoint is substantially equivalent to ORTHOsoft, Inc. Navitrack™ System (K022364) and TraumaCad (K142923, K073714, K042816).

Substantial Equivalence:
Testing performed on this device demonstrates that JointPoint is substantially equivalent to the predicate devices. Performance testing of the JointPoint system included the FDA recommended verification and validation testing. Software verification and validation testing was performed in the laboratory to evaluate setup, accuracy and functionality of the system in supporting orthopedic procedures. Further testing was performed using clinical data to compare the templated versus actual size of the implants in order to validate the system's pre-operative intended use, as well as, cadaver data to validate the system’s intra-operative intended uses.

Conclusion
JointPoint is shown to be substantially equivalent to previously cleared devices with respect to its intended use, indications for use, technological characteristics, and performance characteristics.