ORTHOSIZE

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510(k) Summary

Submitter Name and Address:	Paul Beck Orthosize LLC 939 W. Madison St. Unit 306 Chicago, IL 60607
Date Summary Prepared:	January 10, 2012
Telephone:	(312) 636-8439
Trade Name	Orthosize
Common Name:	Picture and Archiving Communications (PACS) System
Classification and Name:	Image Processing System
Predicate Device:	TraumaCAD 2.0, Orthocrat Ltd. (K073714)

Device Description

Orthosize software uses digital templates, template overlays provided by orthopedic manufacturers, to estimate the size of joints. Orthosize software allows the user to place a template overlay over a radiographic image. The user may then select an overlay that best approximates the size of the joint in the image. The user may also translate and rotate the overlay such that it substantially matches the shape and outline of the joint in the image. In this way, Orthosize software enables the user to estimate the size and shape of implant that most closely approximates the joint presented in the image. Orthosize also allows the user to make simple measurements.

Orthosize software can run on computers using the following operating systems: Windows XP or later, Mac OS X, and iOS.

Indications for Use

Orthosize is indicated for assisting healthcare professionals in preoperative planning of orthopedic surgery. The device allows for overlaying of prosthesis templates on radiological images, and includes tools for performing measurements on the image and for positioning the templates. Clinical judgments and experience are required to properly use the software.

Performance Data

Functional requirements as defined by the Orthosize Software Requirements Specification (SRS) were tested and traceability was performed and documented as defined by FDA's *General Principles of Software Validation* (January 2002) guidance document. Validation included boundary values and stress testing as defined by the FDA's *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices* (May 2005) guidance document. Safety requirements were

tested as identified by a safety risk analysis performed in accordance with ISO 14971:2007. The Orthosize software passed all tests. No test faults were found. Additionally, no test variances were found during testing. Final assessment using a requirements coverage matrix showed that all software requirements were addressed by the tests.

Final evaluation showed that testing of all software requirements was completed with passing results. No software changes were required. Evaluation of the test results demonstrates that the software performs as intended and meets product specifications.

Substantial Equivalence

Orthosize is substantially equivalent to the predicate device. Orthosize software has the same intended use and indications, as well as very similar technological characteristics and principles of operation, in comparison to the predicate device. The minor technological differences between the Orthosize software and its predicate device raise no new issues of safety or effectiveness. Thus, the Orthosize software is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Orthosize LLC
% Ms. Yarmela Pavlovic
Attorney
Hogan Lovells
1835 Market Street, 29th Floor
PHILADELPHIA PA 19103

MAR 14 2012

Re: K120115
Trade/Device Name: Orthosize
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 13, 2012
Received: January 13, 2012

Dear Ms. Pavlovic:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120115

Device Name: Orthosize

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120115

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