

Zimmer Patient Specific Instruments System 5.4
510(k) Premarket Notification

510(k) Summary

K133162

510(k) Summary

The following section is included as required by the Safe Medical Devices Act (SMDA) of 1990 and 21CFR 807.92

Company name	Materialise N.V.
Establishment registration number	3003998208
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City	Leuven
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Country	Belgium
Phone number	+32 16 74 45 37
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Principal Contact person	Oliver Clemens
Contact title	Quality and Regulatory Officer
Contact e-mail address	Regulatory.Affairs@materialise.be
Additional contact person	Wim Claassen
Contact title	Product Manager
Contact e-mail address	Wim.Claassen@materialise.be

Submission date

The date of the Traditional 510(k) submission is September 30th, 2013.

Submission information

<i>Trade Name</i>	Zimmer® Patient Specific Instruments Zimmer® Patient Specific Instruments Planner
<i>Common Name</i>	Knee prosthesis
<i>Classification Name</i>	Knee joint patellofemorotibial polymer /metal /polymer semi-constrained cemented prosthesis
<i>Primary product code</i>	JWH (21 CFR 888.3560)
<i>Subsequent product codes</i>	MBH, OOG and OIY

Predicate Devices

The predicate device to which substantial equivalence is claimed to:

<i>Trade or property or model name</i>	Zimmer® Patient Specific Instruments System 5.0
<i>510(k) number</i>	K121640
<i>Decision date</i>	12/05/2013

<i>Product code</i>	JWH, OOG (21 CFR 888.3560)
<i>Manufacturer</i>	Materialise NV Materialise USA, LLC

Device Description

The subject device *Zimmer*® Patient Specific Instruments System 5.4 is a modification to the predicate device *Zimmer*® Patient Specific Instruments System 5.0 (K121640) to accommodate the new compatible implant system *Zimmer*® *Persona*™ The Personalized Knee System *Trabecular Metal*™ components cleared via 510(k) K122745 and K121771. It is designed to assist a surgeon in the placement of total knee replacement components for *Zimmer*® *Persona*™ *Trabecular Metal*™ components. The system consists of a software device, branded as *Zimmer*® Patient Specific Instruments Planner (ZPSIP) and a hardware component, branded as *Zimmer*® Patient Specific Instruments (ZPSI).

Intended Use

Total Knee Replacement

The *Zimmer*® Patient Specific Instruments System is intended to be used as a surgical instrument to assist in the positioning of Total Knee Replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The *Zimmer*® Patient Specific Instruments System is to be used with *Zimmer NexGen CR-Flex* fixed bearing, *Zimmer NexGen CR* fixed bearing, *Zimmer NexGen LPS-Flex* fixed bearing, *Zimmer NexGen LPS* fixed bearing, *Zimmer Gender Solutions Natural – Knee Flex* fixed bearing, *Zimmer Persona*™ CR fixed bearing, *Zimmer Persona*™ PS fixed bearing and *Zimmer Persona*™ *Trabecular Metal*™ prostheses families only.

Unicompartmental Knee Replacement

The *Zimmer*® Patient Specific Instruments System is intended to be used as a surgical instrument to assist in the positioning of Unicompartmental Knee Replacement components intra-operatively and in guiding the marking of bone before cutting and to guide cutting of the bone provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The *Zimmer*® Patient Specific Instruments System is to be used with *Zimmer Unicompartmental High Flex Knee System* prostheses families only.

The *Zimmer*® Patient Specific Instruments are intended for single use only.

Functioning of the Device

The *Zimmer*® Patient Specific Instruments System 5.4 generates a pre-surgical plan based on MRI image data sets using the *Zimmer Patient Specific Instruments Planner*. The software device then is used pre-operatively by a qualified surgeon to inspect, fine-tune and approve the pre-surgical plan. Next, *Zimmer Patient Specific Instruments* are designed and manufactured based on the approved pre-surgical plan. *Zimmer Patient Specific Instruments* are patient specific templates which transfer the pre-operatively determined positioning of the chosen total knee replacement components to the patient intra-operatively, assisting the surgeon in positioning and aligning the actual total knee replacement components by guiding and marking drill locations.

Technological Characteristics

A detailed comparison shows the subject device is substantially equivalent in intended use, design, functionality, operating principles, materials and performance characteristics to the predicate devices.

Performance Data

Non-clinical tests using saw bones have been performed to assess the safety and effectiveness of the subject device. Testing verified that the accuracy and performance of the system is adequate to perform as intended. Results of software verification and validation testing demonstrated the device's safety and effectiveness is substantially equivalent to the predicate device.

Summary

The characteristics that determine the functionality and performance of the subject device, the *Zimmer* Patient Specific Instruments System 5.4, are substantially equivalent to the device cleared under K121640. The *Zimmer* Patient Specific Instrument System will be manufactured in compliance with FDA and ISO quality system requirements.



February 25, 2014

Materialise N.V.
Mr. Oliver Clemens
Quality and Regulatory Officer
Technologielann 15
Leuven, Belgium 3001

Re: K133162

Trade/Device Name: Zimmer Patient Specific Instruments System 5.4 (Zimmer Patient Specific Instruments Planner, Zimmer Patient Specific Instruments)

Regulation Number: 21 CFR 888.3560

Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Regulatory Class: II

Product Code: JWH, MBH, OOG, OIY

Dated: January 23, 2014

Received: January 27, 2014

Dear Mr. Clemens:

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 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/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133162

Device Name: **Zimmer Patient Specific Instruments System 5.4** (Zimmer Patient Specific Instruments Planner, Zimmer Patient Specific Instruments)

Indications for Use:

Total Knee Replacement

The *Zimmer*[®] Patient Specific Instruments System is intended to be used as a surgical instrument to assist in the positioning of Total Knee Replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

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Unicompartmental Knee Replacement

The *Zimmer*[®] Patient Specific Instruments System is intended to be used as a surgical instrument to assist in the positioning of Unicompartmental Knee Replacement components intra-operatively and in guiding the marking of bone before cutting and to guide cutting of the bone provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The *Zimmer*[®] Patient Specific Instruments System is to be used with *Zimmer Unicompartmental High Flex Knee System* prostheses families only.

The *Zimmer*[®] Patient Specific Instruments are intended for single use only.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

(Division Sign-Off)

Division of Orthopedic Devices

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