2. 510(k) SUMMARY

OCT 12 2012

Sponsor Name: Consensus Orthopedics, Inc.
1115 Windfield Way, Suite 100
El Dorado Hills, CA 95762

510(k) Contact: Matthew M. Hull, RAC
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Date Prepared: 11 October 2012

Trade Name: UNISYN Plus stem

Common Name: Stem, modular hip prosthesis.

Device Class: 2

Classification Name: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented (21 CFR 888.3360, LWJ)

Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (21 CFR 888.3350, JDI)

Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented (21 CFR 888.3353, LZO)

Device Description:

The UniSyn Hip System was originally cleared as a modular hip system for Hayes Medical under the name "Triton", modifications to the system were cleared in a subsequent submission by Hayes under the UniSyn name. Hayes Medical changed its name to Consensus Orthopedics in 2008. This system consists of three primary components: the neck, the body, and the stem. This submission is to address the addition of a set of modified ("Plus") stems.

These minor modifications in body thickness are designed to allow for better contact between the implant and the inner surface of the medullary canal during revision surgery. The sizes of stems offered with the modified design are within the ranges previously cleared for the UniSyn system. The Plus stems are offered in neutral or +1mm styles, short or long, in 10 to 20 mm diameters, and lengths from 110 to 210 mm. There is no change to the manufacturing, packaging, or sterilization processes. This change will not affect the indications for use nor any of the labeling.

K120595

Indications for Use:
A) Significantly impaired joints resulting from rheumatoid, osteo, and posttraumatic arthritis.
B) Revision of failed femoral head replacement, hip arthroplasty or other hip procedures.
C) Proximal femoral fractures.
D) Avascular necrosis of the femoral head.
E) Non-union of proximal femoral neck fractures.
F) Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, pseudarthrosis conversion, and structural abnormalities.

UNISYN stems used with roughened and plasma coated bodies are intended for cemented or uncemented use. UNISYN stems used with plasma/HA or HA coated bodies are intended for uncemented use only.

Substantial Equivalence:

Technological Characteristics/Substantial Equivalence:
The new "Plus" stems for the UniSyn hip systems employ the same materials, basic design features, manufacturing processes, packaging, and indications as the predicate stems for the UHS. Therefore, the new Plus stems for use with the UNISYN Hip System are substantially equivalent to legally marketed predicate devices (Table 2.1).

Table 2.1: Legally marketed devices to which substantial equivalence is claimed:

510(k) Number	Trade Name	510(k) holder	510(k) Release Date
K003649	Triton Hip System	Hayes Medical, Inc.	02/23/2001
K062383	UniSyn HA Plasma Modular Hip	Hayes Medical, Inc.	12/21/2006

Non-Clinical Performance Data:
The UNISYN Hip System (UHS) implant components use the identical materials, design construct features of the predicate components. The UHS implant components were evaluated using a Failure Modes and Effects Analysis (FMEA). Distal fatigue performance of the UniSyn Plus grit blasted stem was evaluated per ISO 7206-4 on a worst case example. No other non-clinical bench testing was deemed necessary over that used in support of the predicates based on identical design and materials.

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

OCT 12 2012

Consensus Orthopedics, Incorporated
% Mr. Matthew M. Hull, RAC
Director, QS and RA
1115 Windfield Way, Suite 100
El Dorado Hills, California 95762

Re: K120595
Trade/Device Name: UNISYN Hip System
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi hip) metallic cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: LWJ, JDI, LZO
Dated: October 4, 2012
Received: October 5, 2012

Dear Mr. Hull:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Enclosure

K120595

1. INDICATIONS FOR USE STATEMENT

510(k) Number: K120595

Device Name: UNISYN Hip System

Indications for Use:

Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis. Revision of failed femoral head replacement, hip arthroplasty or other hip procedures.

A. Proximal femoral fractures.
B. Avascular necrosis of the femoral head.
C. Non-union of proximal femoral neck fractures.
D. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, pseudarthrosis conversion, and structural abnormalities.

UNISYN™ assemblies with roughened and plasma coated bodies are intended for cemented or uncemented use. UNISYN™ assemblies with plasma/HA or HA coated bodies are intended for uncemented use only.

Prescription Use ___X___	AND/OR	Over the Counter Use ____.
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120595