510(k) SUMMARY

GenOssis, LLC

OptOssol™ Compression Device System

Sponsor:	Manufacturer	GenOssis LLC 426 Pennsylvania Avenue, Suite 120 Fort Washington, PA 19034
	Official Contact Phone: Fax:	Barry E. Sands 978-358-7307 978-358-7384
	Date prepared:	April 1, 2014
Device Name:	**OptOssol™ Compression Device System**	
Classification Name:	**Smooth or Threaded Metallic Bone Fixation Fastener** **Single/multiple Component Metallic Bone Fixation Appliances and Accessories**	
Classification Number:	**21 CFR Sec. 888.3030 and 21 CFR 888.3040** **Class 2** **Product Code: HTN, JDW and HWC**	
Description:	The **GenOssis OptOssol™ Compression Device System** implants consists of screws designed to compact juxtaposed bone fragments in compression to enhance bone healing and fusion through the immobilization of the fragments with or without the use of bone graft. The wires are inserted using standard wire drivers present in the operating room and compression is conducted using the provided driver. The partially threaded Wires are available with a Sleeve, and in various diameters and lengths to accommodate patient anatomy.	
Intended Use:	The **OptOssol™ Compression Device System** is indicated for use in the internal fixation of fractures, fusions and revisions, The system is intended for but not limited to hand surgery, orthopedic surgery and podiatric surgery - but is not intended for Spinal Use.	
Material:	The **OptOssol™Compression Device System** is composed of 316 LVM ASTM F138. The material composition has been established as a biocompatible material for orthopedic permanent implants.	

	The instruments associated with the **OptOssol™ Compression Device System** are composed of 17-4PH Stainless Steel and Custom 465® Stainless Steel (ASTM F899). Both of these tissue-contacting materials have an established biocompatible profile for surgical instruments in orthopedics.
Comparison to Predicate Devices	OptOssol™ Compression Device System has the same intended use as the predicate device contained in K130298. The technological characteristics of material composition and dimensional specifications fall within the range of the predicate devices identified. Therefore, the OptOssol™ Compression Device System is equivalent to the predicate devices identified.
Performance Data:	Mechanical tesing was performed per ASTM F543:2013 Standard Specification and Test Methods for Metallic Medical Bone Screws.
Performance and SE Determination:	Based upon the results of the performance testing the OptOssol™ Compression Device System was determined to be substantially equivalent to the predicate devices.

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

May 30, 2014

GenOssis, LLC
% Mr. Barry E. Sands
RQMIS, Incorporated
29 Water Street, Suite 305
Newburyport, Massachusetts 01950

Re: K140875
Trade/Device Name: GenOssis OptOssol™ Compression Device System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: JDW, HTN, HWC
Dated: April 2, 2014
Received: April 4, 2014

Dear Mr. Sands:

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,

Ronald P. Jean -S for

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K140875

Device Name: **GenOssis OptOssol™ Compression Device System**

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Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Elizabeth L. Frank -S

Division of Orthopedic Devices