510(k) SUMMARY

K091992

EIDOSMED LLC

DEC - 9 2009

EDG Depth Gauge

Date Prepared	September 30, 2009
Summay prepared by:	John Kim Eidosmed LLC 2312 Wabansia Unit 1 Chicago IL 60647 Phone: (312) 450-5143 (P) johnkim@eidosmed.com
Applicant	EIDOSMED LLC 2312 Wabansia Unit 1 Chicago IL 60647 Phone: (312) 450-5143 Fax (312) 277-6464
Device Name	Electronic Depth Gauge
Trade Name	EDG
Common Name	Depth Gauge
Classification	Class: II Product Code: OOL Regulation: 21 CFR 888.3030
Identification of Predicate Devices and Summary of Substantial Equivalence	The Electronic Depth Gauge is substantially equivalent with respect to intended use, design, risks, device characteristics and performance aspects to: Acromed Interbody Depth Gauges, K873191 Buckman Co., Inc.
Device Description	The Eidosmed Electronic Depth Gauge ("EDG") is a depth gauge measuring device intended for various medical purposes, including but not limited to, measuring the depth of a passageway in a bone or other tissue to enable insertion of properly sized screws and implants. In addition to mechanically measuring and displaying depth using an analog scale, the EDG displays this information using a digital readout. The EDG, referred to as the EDG 4.0 version, is a completely disposable device. It is intended to be used on one patient, over the course of one surgical procedure.

Intended Use and Indications	The Eidosmed EDG is a depth gauge measuring device intended for various medical purposes including but not limited to, measuring the depth of a passageway in a bone or other tissue to enable insertion of properly sized screws and implants.
Technological Characteristics and Substantial Equivalence	The Eidosmed EDG has many similar technological characteristics and is substantially equivalent to the predicate. The method of use for the EDG device is exactly the same as the predicate. Both devices use a hook inserted, in a linear motion, into the passageway until the indented hook purchases the distal end of the bone. The user then visually aligns the thumb slide with the analog scale printed on the outer housing, correlating to the depth of the bone. Finally, the hook is removed from the passageway. The material used in the EDG is also similar to those used in the predicate. Both devices use medical grade 316 stainless steel for the probe/hook inserted into the bone or tissue. The Lexan plastic has been evaluated and found compliant to the most stringent biocompatibility test standards. Both the EDG and the predicate device have GR&R values well below the 10% industry benchmark.
Performance Testing/Data	Tests were performed on the device which demonstrated that the device is safe and effective, performs comparably to and is substantially equivalent to the predicate device. The results for the Gauge R & R testing resulted in a statistically significant value of 2.48% which signifies excellent precision. Additionally, the accuracy of EDG outperformed the accuracy of the analog device (with an alpha = .0005). Because both the EDG and the predicate device have below 10% values for GR&R, it can be concluded that the devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Eidosmed, LLC
% Mr. Daniel Kamm
Kamm & Associates
8726 Ferrara Ct.
Naples, Florida 34114

DEC 9 2009

Re: K091992
Trade/Device Name: Eidosmed, Model EDG4.0
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: 'OOL
Dated: October 31, 2009
Received: November 3, 2009

Dear Mr. Kamm:

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 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,

for

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K091992

Device Name: Electronic Depth Gauge (EDG):

The Eidosmed EDG is an electronic depth gauge, a measuring device intended for various medical purposes including, but not limited to, measuring the depth of a passageway in a bone or other tissue. The EDG enables the proper sizing of screws and implants in medical procedures.

Prescription Use X AND/OR Over-The-Counter Use ____.
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K091992