JUL 15 2014

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K133053

7.1 Date of Submission

07/14/2014

7.2 Sponsor Identification

Weigao Orthopaedic Device Co., Ltd.
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7.3 Designated Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu

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7.4 Identification of Proposed Device

Trade Name: Milestone™ Spinal System
Common Name: Intervertebral Body Fusion Device

Regulatory Information:
Classification Name: Intervertebral body fusion device
Classification: II;
Product Code: MAX;
Regulation Number: 21 CFR 888.3080;
Review Panel: Orthopedic;

Intended Use Statement:

The Milestone™ Spinal System is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved level. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via transforaminal approach. These implants are to be used with autogenous bone graft.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

7.5 Device Description

The Milestone Spinal System consists of INVIBIO PEEK-OPTIMA LT1 lumbar cages of various lengths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. They are designed with angular teeth to allow the implant to grip the superior and inferior end plates. The hollow geometry of the implants allows them to be packed with autogenous bone graft in lumbar interbody fusion procedures. The cages contain radiographic tantalum markers used for both intra and post-operative positioning and visualization. The cages are provided sterile. The Milestone Spinal System also includes various device specific instruments which are provided non-sterile.

7.6 Identification of Predicate Device

510(k) Number: K073291
Product Name: CAPSTONE® Spinal System
Manufacturer: Medtronic Sofamor Danek USA, Inc.

7.7 Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO11137-2:2012, Sterilization of healthcare products-Radiation-Part 2: Establishing the sterilization dose;
- USP <85> Bacterial Endotoxin Limit;
- ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials;
- ASTM F 2077-03 Test Methods For Intervertebral Body Fusion Devices

7.8 Clinical Test Conclusion

No clinical study is included in this submission.

7.9 Substantially Equivalent (SE) Comparison

Table 6-1 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device(s)
Product Code	MAX	MAX
Regulation Number	21 CFR 888.3038	21 CFR 888.3038
Intended Use	The Milestone™ Spinal System is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved level. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via transforaminal approach. These implants are to be used with autogenous bone graft.	The CAPSTONE® Spinal System is indicated for with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transformational approach. These

		DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.	implants are intended to be used with supplement fixation instrumentation, which has been cleared by the FDA for use in lumbar spine.
Sterile		Radiation Sterilized	Radiation Sterilized
Single Use		Yes	Yes
Shelf Life		4 years	4 years
Performance		Comply with ASTM F2077-03	Comply with ASTM F2077-03
Features		a convex, bullet nose design	a convex, bullet nose design
		angular teeth	angular teeth
		hollow geometry	hollow geometry
Patient contact material	Cage	INVIBIO PEEK-OPTIMA LTI	PEEK
	Instrument	630 Stainless Steel	630 Stainless Steel
	radiographic maker	tantalum	tantalum
Physical specification	Height	8mm, 10mm, 12mm,14mm	8mm, 10mm, 12mm,14mm
	Length	22mm, 26mm, 32mm,36mm	22mm, 26mm, 32mm,36mm

7.10 Substantially Equivalent (SE) Conclusion

Based on the comparison above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.

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

July 15, 2014

Weigao Orthopaedic Device Company, Limited
% Ms. Diana Hong
Mid-Link Consulting Company, Limited
P.O. Box 120-119
Shanghai, 200120, CHINA

Re: K133053
Trade/Device Name: Milestone Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 13, 2014
Received: June 16, 2014

Dear Ms. Hong:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133053

Device Name
Milestone Spinal System

Indications for Use *(Describe)*

The Milestone Spinal System is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved level. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via transforaminal approach. These implants are to be used with autogenous bone graft.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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