510(k) Summary

The following 510(k) summary is submitted as required by 21 CFR Part 807.92:

Date Prepared: Feb 21, 2012

1. **Submission information:**

a) Submitter

Name	BM KOREA CO., LTD.
Address	325-26 Dangjeong-dong, Gunpo-si, Gyeonggi-do 435-832 South Korea
Phone	82-31-451-9294~5
Fax	82-31-451-9248
Contact	Ju Yun

b) U.S Agent

Name	LK Consulting Group
Address	951 Starbuck St. Unit J, Fullerton, CA 92833
Phone	714-869-3080
Fax	714-409-3357
Contact	Priscilla Chung

2. **Device Identification:**

Trade Name: SYNSTER® CERVICAL CAGE
SYNSTER® ALIF CAGE
SYNSTER® PLIF CAGE
SYNSTER® PTLIF CAGE
SYNSTER® TLIF CAGE

Common Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral Fusion Device with Bone Graft, Cervical
(21 CFR 880.3080, Product Code ODP)
Intervertebral Fusion Device with Bone Graft, Lumbar
(21 CFR 880.3080, Product Code MAX)

3. **Identification of the Legally Marketed Devices (Predicate):**

Substantial Equivalence for the SYNSTER® (CERVICAL, ALIF, PLIF, PTLIF and TLIF) CAGE is based on its similarities in indications for use, design features, operational principle and material composition when compared to the predicate devices cleared under the following:

Eminent Spine Interbody Fusion System (K090064)
Genesys Spine Interbody Fusion System (K103034)

BAK/Cervical Interbody Fusion System (P980048)
Affinity Anterior Cervical Cage System (P000028)
RAY Threaded Fusion Cage (P950019)
Lumbar I/F Cage (P960025)
INTERFIX Threaded Fusion Device (P970015)
RABEA™ Spinal Implant (K082848)
Aesculap PEEK Spinal Implant System (K071983)
Stryker Spine AVS® TL PEEK Spacers (K083661)
Synthes T-PAL Spacer (K100089)
AVS® PL PEEK Spacers (K093704)
AnyPlus ALIF, PLIF, TLIF PEEK Lumbar Cage (K100516)

4. Device Description:

The SYNSTER® (CERVICAL, ALIF, PLIF, PTLIF and TLIF) CAGE will be offered in various device configurations based on surgical approach and patient anatomy, and consist of:

1) Cervical Interbody Fusion Device (SYNSTER® CERVICAL CAGE), which may be implanted as a single device via an anterior approach.

2) Lumbar Interbody Fusion Device [SYNSTER® (ALIF, PLIF, PTLIF and TLIF) CAGE], which may be implanted
   - As a single device via an Anterior or Anterolateral or Lateral (ALIF) approach;
   - Bi-laterally via a posterior (PLIF) approach;
   - As a single device via a posterior transforaminal (PTLIF) approach;
   - As a single device via a transforaminal (TLIF) approach.

The SYNSTER® (CERVICAL, ALIF, PLIF, PTLIF and TLIF) CAGE components are made of polyether ether ketone (PEEK Optima LT1) that conforms to ASTM F2026. Additionally, the devices contain titanium makers (ASTM F136) to assist the surgeon with proper placement of the device.

The SYNSTER® (CERVICAL, ALIF, PLIF, PTLIF and TLIF) CAGE is implanted by using the (SCCI, SACI, SPCI, SPTCI and STCI) instruments manufactured from stainless steel materials that conform to ASTM F899.

5. Indications for Use:

The SYNSTER CERVICAL CAGE is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The SYNSTER (ALIF, PLIF, PTLIF and TLIF) CAGE is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at one level or two continuous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic

origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

6. Summary of Technology Characteristics:

The purpose of this premarket notification is to obtain clearance to market the SYNSTER® (CERVICAL, ALIF, PLIF, PTLIF and TLIF) CAGE. The SYNSTER® (CERVICAL, ALIF, PLIF, PTLIF and TLIF) CAGE is comprised of various device configurations designed to accommodate patient anatomy and provide the surgeon with different surgical approach options.

The SYNSTER® (CERVICAL, ALIF, PLIF, PTLIF and TLIF) CAGE Implant components are made of polyether ether ketone (PEEK Optima LT1) that conforms to ASTM F2026. Additionally, the devices contain titanium makers (ASTM F136) to assist the surgeon with proper placement of the device.

The subject system has similar technological characteristics as the predicate devices identified above. Specifically, the following characteristics support this conclusion;

- Intended for use at one level from the C2-C3 disc to the C7-T1 disc for the treatment degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at the involved level.
- Intended for use at either one level or two contiguous levels from L2-S1 for the treatment of degenerative disc disease (DDD) with up Grade I spondylolisthesis or retrolisthesis at the involved level(s).
- Substantially equivalent result of non-clinical testing relative static and dynamic testing (per ASTM F2077-03), subsidence testing (per ASTM F2267-04), and expulsion testing (per ASTM Draft Standard F 04.25.02.02)

7. Discussion of Non-clinical Testing

The following non-clinical tests were conducted:

- Static and dynamic compression testing, static compression shear testing, conducted in accordance with ASTM F2077-03
- Static and dynamic torsion testing, conducted in accordance with ASTM F2077-03
- Subsidence testing, conducted in accordance with ASTM F2267-04
- Expulsion testing (per ASTM Draft Standard F 04.25.02.02)

8. Conclusions

The subject and predicate device(s) share the same intended use, primary implant design and equivalent material of manufacture. Tests performed according to ASTM F2077/F2267 indicate that The SYNSTER® (CERVICAL, ALIF, PLIF, PTLIF and TLIF) CAGE meet required mechanical strengths. Some of the predicate devices have a different geometry than The SYNSTER® (CERVICAL, ALIF, PLIF, PTLIF and TLIF) CAGE. But the non-clinical mechanical test results demonstrate that any minor differences do not impact performance as compared to the predicates and demonstrate that The SYNSTER® (CERVICAL, ALIF, PLIF, PTLIF and TLIF) CAGE is substantially equivalent to the predicate device.

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

BM KOREA CO., LTD.
% LK Consulting Group
Ms. Priscilla Chung
951 Starbuck Street, Unit J
Fullerton, California 92833

MAR 1 4 2012

Re: K111820
Trade/Device Name: SYNSTER® CERVICAL CAGE
SYNSTER® ALIF CAGE
SYNSTER® PLIF CAGE
SYNSTER® PTLIF CAGE
SYNSTER® TLIF CAGE
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: March 1, 2012
Received: March 8, 2012

Dear Ms. Chung:

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

Indications for Use

510(k) Number (if known) K111820

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Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21CFR 801 Subpart D) (21CFR 801 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)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111820