K113509

JAN 2 0 2012

L&K BIOMED

510(k) SUMMARY

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

1. **Submitter:** L&K BIOMED Co., Ltd.
#1104, Ace High-end Tower 3 cha, 371-50, Gasan-Dong,
Geumcheon-gu, Seoul 153-803 Republic of Korea
Phone. 82-2-2624-1471
FAX .82-2-2624-1477

Contact Person: Hee Kyeong Joo

Prepared Date November 24, 2011

2. **Device Identification**

Trade Name	LEXUS Anterior Cervical Plate System
Common Name	Anterior Cervical Plate
Classification Name	Spinal Intervertebral Body Fixation Orthosis
Regulation Number	21 CFR 888.3060
Product Code	KWQ
Device Classification	Class II

3. **Identification of Legally Marketed Devices**
   - **U&I Corporation**: Maxima™ Anterior Cervical Plate System (K061002)
   - **Synthes:** Synthes Anterior Cervical Locking Plate(ACLP) System (K031276)
   - **Medtronic:** ZEPHIR™ Anterior Cervical Plate System(K994239, K030327)

4. **Description of the Device**

The LEXUS Anterior Cervical Plate System is composed of plates and screws which are made from titanium alloy Ti-6Al-4V ELI (ASTM F136). These plates attach to the anterior cervical spine with a minimum of four screws per plate. The plates range in length to accommodate one, two, three, and four level procedures. The screws in the LEXUS Anterior Cervical Plate System are 3.5mm and 4.0mm diameter bone screws. They are fixed self-tapping, variable self-tapping, fixed self-drilling, variable self-drilling and are available in lengths ranging from 12 to 20mm.

5. Intended use

The LEXUS Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7). The System is indicated for use in the immobilization and stabilization of the spine as an adjunct to fusions in patients with:

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- spondylolisthesis,
- trauma (i.e. fractures or dislocations),
- tumors,
- deformity (defined as kyphosis, lordosis or scoliosis),
- pseudarthrosis,
- failed previous fusion,
- spinal stenosis.

6. Comparison of the Technology Characteristics

The LEXUS Anterior Cervical Plate System shares technological characteristics similar to the predicate devices. These characteristics include similar design, the same materials, substantially equivalent performance characteristics and the same intended use.

7. Discussion of the Non-Clinical Testing

Static compression bending, tension, torsion and dynamic compression bending were performed according to ASTM F1717 on a worst-case, cervical plate construct. The mechanical test results demonstrated that the LEXUS Anterior Cervical Plate System performs as well as the predicate device.

8. Conclusion

The LEXUS Anterior Cervical Plate System is substantially equivalent to the device referenced above and is therefore safe and effective for its intended use.

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

JAN 2 0 2012

L & K Biomed Co., LTD
% Ms. Hee Kyeong Joo
Room 1104, Ace High-End Tower 3,
371-50 Gasan-Dong, Geumcheon-gu,
Seoul 153-803, Republic of Korea

Re: K113509
Trade/Device Name: LEXUS Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: November 24, 2011
Received: November 28, 2011

Dear Ms. Hee Kyeong Joo:

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

K113509

Indications for Use Statement

510(k) Number (if known): K113509

Device Name: LEXUS Anterior Cervical Plate System

Indications For Use:

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- pseudarthrosis,
- failed previous fusion,
- spinal stenosis.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____

(Part 21 CER801 Subpart D) (21 CER801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (OED)

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

510(k) Number K113509