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

JAN 1 0 2017

Mr. Robert Kelly
C Change Surgical, LLC
101 N. Chestnut Street, Suite 301
Winston-Salem, NC 27101

Re: K051819
Trade/Device Name: C Change Solution Warmer
Regulation Number: 21 CFR 890.5950
Regulation Name: Powered Heating Unit
Regulatory Class: Class I
Product Code: LHC
Dated: July 1, 2005
Received: July 7, 2005

Dear Mr. Kelly:

This letter corrects our substantially equivalent letter of August 15, 2005.

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 Parts 801 and 809 ); 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 Parts 801 and 809), 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" (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 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,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K051819

Device Name: C Change Solution Warmer

Indications for Use:

The C Change Solution Warmer is designed to warm and maintain the temperature of surgical solutions prior to their use.

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucknell for Mel Kerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices



510(k) Number K051819

**510(k) Summary**
**Integrity Spine Lumbar Interbody Fusion System**
**Premarket Notification**

| | |
|---|---|
| **SUBMITTED BY** | Integrity Spine<br>2800 NE Loop 410 Suite 203<br>San Antonio, TX 78218 |
| **ESTABLISHMENT REGISTRATION NUMBER** | 3010763958 |
| **OWNER/OPERATOR NUMBER** | 10046086 |
| **CONTACT PERSON** | Lisa Peterson<br>Kaedon Consulting, LLC<br>Phone: 512-507-0746<br>Fax: 512-266-3364<br>lpeterson@kaedonconsulting.com |
| **DATE PREPARED** | October 12, 2015 |
| **CLASSIFICATION NAME** | Intervertebral Body Fusion Device |
| **DEVICE CLASS** | Class II |
| **REGULATION NUMBER** | 888.3080 (Product Code MAX) |
| **COMMON NAME** | Intervertebral Fusion Device with Bone Graft, Lumbar |
| **PROPRIETARY NAME** | Integrity Spine Lumbar Interbody Fusion System |

**IDENTIFICATION OF PREDICATE DEVICE(S)**

Predicate devices include various cleared interbody fusion systems:

**Primary**

- DiFusion: Xiphos Interbody Fusion System (K100042)

**Secondary**

Additional Predicate

- DePuy Acromed: Lumbar I/F Cage (P960025)

Reference Devices

- Eminent Spine: Eminent Spine Interbody Fusion System (K090064)
- Medtronic: InterFix System (P970015)
- SeaSpine: SeaSpine Spacer System (K082310)
- Tyber Medical: Tyber Medical Interbody System (K130573)
- Spinal USA: Spinal USA Interbody Fusion Device (K092193)

**DEVICE DESCRIPTION**

The Integrity Spine Lumbar Interbody Fusion System will be offered in various device configurations based on surgical approach and patient anatomy. The Integrity Spine lumbar interbody fusion device(s) may be implanted:

- bi-laterally in pairs via a posterior (PLIF) approach;
- as a single device via an oblique (OLIF) approach;
- as a single device via a transforaminal (TLIF) approach; or
- as as a single device via an anterior or anterolateral (ALIF) approach.

The System is implanted using a combination of device specific and universal class I instruments manufactured from stainless steel materials that conform to ASTM F899.

**INDICATIONS**

The Integrity Spine Lumbar Interbody Fusion System 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 either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

**SUMMARY OF TECHNOLOGICAL CHARACTERISTICS**

The purpose of this premarket notification is to obtain clearance to market the Integrity Spine Lumbar Interbody Fusion System. The Integrity Spine System is comprised of various device configurations based on surgical approach and patient anatomy. The implant components are made of polyether ether ketone (PEEK Zeniva ZA-500) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers (ASTM F560) 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 either one level or two contiguous levels, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).
- Substantially equivalent results of non-clinical testing relative to static and dynamic testing (per ASTM F2077-11 ), subsidence (per ASTM F2267-04), and expulsion (per ASTM Draft Standard F-04.25.02.02)

**DISCUSSION OF NON-CLINICAL TESTING**

The following non-clinical tests were conducted:

- Static and dynamic compression testing, conducted in accordance with ASTM F2077-11
- Static and dynamic torsion testing, conducted in accordance with ASTM F2077-11
- Subsidence testing, conducted in accordance with ASTM F2267-04
- Expulsion testing, conducted in accordance with ASTM Draft Standard F-04.25.02.02

**CONCLUSIONS**

The subject and predicate device(s) share the same intended use, primary implant design and equivalent material of manufacture. The non-clinical mechanical test results demonstrate that any minor differences do not impact device performance as compared to the predicates and demonstrate that the Integrity Spine Lumbar Interbody Fusion System is substantially equivalent to the predicate device.