Dear Bret Berry:

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 (DICE) 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 (DICE) 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,

Mark N. Melkerson -S

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

Enclosure
Indications for Use

The Reliance Cervical IBF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The Reliance Cervical IBF and Reliance Cervical IBF-HA implants are intended to be used with legally cleared supplemental spinal fixation cleared for the implanted level.

The Reliance Cervical IBF System is intended for use at one level in the cervical spine, from C3 to T1, for treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The Reliance Cervical IBF System is to be used in patients who have six weeks of non-operative treatment.

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)
Section 6: 510(k) Summary

Reliance Medical Systems, LLC
545 West 500 South
Suite 100
Bountiful, UT 84010
Telephone: (801) 295-3280
Fax: (801) 294-0079

Contact: Bret M. Berry, Member-Manager

Common or Usual Name: Intervertebral Body Fusion Device
Proposed Proprietary or Trade Name: Reliance Cervical IBF System
Classification Name: Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Product Code: ODP, OVE

Substantial Equivalence:

The subject Reliance Cervical IBF System is substantially equivalent to the legally marketed predicate device, the Reliance Cervical IBF System (K120396/K142269). The subject Reliance Cervical IBF System is equivalent to its predicate in terms of intended use, indications for use, design, function, principle of operation, materials, levels of attachment, size range, and use with supplemental fixation.

Device Description:

The Reliance Cervical IBF System is comprised of implant and instrument components. The Reliance Cervical IBF, the implant component, is a spacer which inserts between vertebral bodies in the anterior column of the cervical spine. The Reliance Cervical IBF spacer is either comprised of PEEK Optima HA with Tantalum markers, or from PEEK Optima LT1 with Tantalum markers. The Reliance Cervical IBF-S spacer (PEEK Optima LT1 or PEEK Optima HA) also incorporates screws to better fixate and stabilize the spine. These screws are manufactured from Titanium alloy as described by ASTM F-136. The device is intended for interbody fusion in the cervical spine and to aid in the surgical correction and stabilization of the spine.

Intended Use / Indications for Use:

The Reliance Cervical IBF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The Reliance Cervical IBF and Reliance Cervical IBF-HA implants are intended to be used with legally cleared supplemental spinal fixation cleared for the implanted level.
The Reliance Cervical IBF System is intended for use at one level in the cervical spine, from C3 to T1, for treatment of cervical disc disease (defined at neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The Reliance Cervical IBF System is to be used in patients who have six weeks of non-operative treatment.

**Technological Modifications:**

The subject Reliance Cervical IBF system offers additional components. These include additional sizes for the Reliance IBF-VBS PEEK implant designs, specifically a 14x11mm size. Since its last clearance, Reliance has made minor modifications to the Reliance Cervical IBF System which were assessed and determined to not affect the safety and effectiveness of the device. A description of these changes have been included to provide a current and comprehensive description of the device.

There have been no changes to intended use, indications for use, function, principle of operation, materials, levels of attachment, or method of insertion.

**Performance Data and Substantial Equivalence:**

Based on risk analysis and FEA analysis, the 14x11mm size was determined to not present a new worst-case test condition for mechanical testing, performance testing, sterilization, cleaning or packaging. Therefore, in accordance with the design control process, additional performance data was not necessary for the changes subject of this Special 510(k).