Choice Spine, LP.
% Meredith May
Senior Manager
Empirical Consulting
4628 Northpark Drive
Colorado Springs, Colorado 80918

October 23, 2017

Re: K171489
Trade/Device Name: Acapella Cervical Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: August 22, 2017
Received: August 23, 2017

Dear Ms. May:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K171489

Device Name
Acapella Cervical Spacer System

Indications for Use *(Describe)*

The Choice Spine Acapella Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one disc level from C2-T1. Degenerative Disc Disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Choice Spine Acapella Cervical Spacer System is to be used with autogenous bone graft and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach.

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)*

510(K) SUMMARY

Submitter's Name:	Choice Spine, LP.
Submitter's Address:	400 Erin Dr. Knoxville, TN 37919
Submitter's Telephone:	865.246.3333
Contact Person:	Meredith L. May MS, RAC Empirical Consulting 719.337.7579
Date Summary was Prepared:	19 May 2017
Trade or Proprietary Name:	Acapella Cervical Spacer System
Common or Usual Name:	Interbody Spacer
Classification:	Class II per 21 CFR §888.3080 Intervertebral Body Fusion Device
Product Code:	OVE

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Choice Spine Acapella Cervical Spacer System is an anterior cervical interbody device consisting of a PEEK (polyetheretherkeytone) implant cage with tantalum radiographic markers and two titanium alloy internal anchors. It is intended for use as an interbody fusion device and is offered in a variety of heights, footprints, and lordotic angles to accommodate varying anatomical conditions. The Choice Spine Acapella Cervical Spacer System is to be used with autogenous bone graft and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach

Acapella Cervical Spacer System implants are composed of PEEK Optima Grade LT1, Ti-6Al-4V, and tantalum. The body of the implant is composed of PEEK Optima Grade LT1 (ASTM 2026). The PEEK Optima Grade LT1 used in Acapella implants is manufactured using the same processes used to manufacture Acapella One implants (K132582).

The material used to construct the anchors is titanium alloy Ti-6Al-4V per ASTM F136, which has a long history of safe and effective use in orthopedic implants.

The radiographic markers are composed of tantalum per ASTM F560, which has a long history of safe and effective use in orthopedic implants.

The locking pins are composed of nitinol per ASTM F2063, which has a long history of safe and effective use in orthopedic implants.

The Acapella Cervical Spacer System is accompanied by a complete instrumentation system to assist the surgeon in the implantation of the device.

INDICATIONS FOR USE

The Choice Spine Acapella Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one disc level from C2-T1. Degenerative Disc Disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Choice Spine Acapella Cervical Spacer System is to be

used with autogenous bone graft and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Principles of operations
- Dimensional characteristics
- Two titanium internal anchors
- Indications for use
- Materials of manufacture
- Structural support mechanism
- Radiographic markers
- Sterilization

Table 5-1: Predicate Devices

510(k) Number	**Trade or Proprietary or Model Name**	**Manufacturer**	
K132582	Acapella™ One Cervical Spacer System	Exactech®	Primary
K170953	TOMCAT™ Cervical Spinal System	Choice Spine, LP.	Additional

PERFORMANCE DATA

The modified Cervical Spacer System has been tested in the following test modes:

- Static axial compression per ASTM F2077-11
- Static compressive shear per ASTM F
- Static torsion per ASTM F2077-11
- Static subsidence per ASTM F2267-04
- Static expulsion per ASTM F-04.25.02.02 (draft)
- Dynamic axial compression bending per ASTM F2077-11
- Dynamic compressive shear per ASMT F2077-11
- Dynamic torsion per ASTM F2077-11
- Custom static tension testing

The results of this non-clinical testing show that the strength of the Cervical Spacer System is substantially equivalent to the legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Cervical Spacer System is substantially equivalent to the predicate and previously cleared devices.