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

April 21, 2017

Choice Spine, LP
Kim Finch
Manager of Regulatory Affairs
400 Erin Drive
Knoxville, Tennessee 37919

Re: K170953
Trade/Device Name: TOMCAT™ Cervical Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: March 29, 2017
Received: March 31, 2017

Dear Ms. Finch:

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 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 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,

Vincent J. Devlin -S

for
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170953

Device Name
TOMCAT™ Cervical Spinal System

Indications for Use *(Describe)*

The TOMCAT™ Cervical Spinal System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients. The interbody is used with bone screws provided and requires no additional supplementary fixation. The interbody is inserted between the vertebral bodies into the disc space at one or two contiguous levels from the C2/C3 disc space to the C7/T1 disc space for the treatment of cervical degenerative disc disease. Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history or radiographic studies. The device system is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and /or corticocancellous bone graft, to facilitate fusion. The device is implanted by an anterior approach. The TOMCAT™ implant must be used with the screws included in the TOMCAT™ system. This device is to be used in patients who have had 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

7. 510(k) Summary

I. Submitter

Choice Spine, LP.

400 Erin Drive

Knoxville, TN 37919

Phone: 865-246-3333

Fax: 865-246-3334

Contact Person: Kim Finch, Manager of Regulatory Affairs

Contact Email: kfinch@choicespine.com

Date Prepared: March 30, 2017

II. Device

Name of Device: TOMCAT™ Cervical Spinal System

Classification Name: Intervertebral Body Fusion Device

Product Class: Class II

Regulatory Number: 21 CFR 888.3080

Regulation Name: Intervertebral Body Fusion Device

Product Code: OVE

Panel Code: 87- Orthopedics Devices

III. Predicate Device

The TOMCAT™ Cervical Spinal System K152515 is the primary predicate device provided for this submission.

IV. Device Description

The TOMCAT™ Cervical Spinal System is an anterior cervical spinal fixation system for an effective means of stabilizing the cervical vertebral column (C2-T1) as an adjunct to fusion of vertebral bodies. The TOMCAT™ System will provide an alternative to the more common cervical plate and cervical interbody spacer Anterior Cervical Discectomy & Fusion (ACDF) surgical procedure. The TOMCAT™ Cervical Spinal System is a radiolucent and radiopaque intervertebral body fusion device. The interbody is made from PEEK per ASTM F2026 with titanium alloy (Ti-6Al-4V ELI) per ASTM F136, tantalum radiopaque markers per ASTM F560, and nitinol clips per ASTM F2063. This device accepts titanium (Ti-6Al-4V ELI) bone screws that are available in two diameters and multiple lengths.

The system will be composed of a cervical interbody spacer with a zero profile and a hybrid profile design. The hybrid device is implanted anteriorly by inserting two screws,

one screw into the anterior face of vertebral body and the other diagonally though the end plate. The zero profile device implants are implanted anteriorly and stabilized by two diagonally placed screws.

V. Indications for Use

The TOMCAT™ Cervical Spinal System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients. The interbody is used with bone screws provided and requires no additional supplementary fixation. The interbody is inserted between the vertebral bodies into the disc space at one level from the C2/C3 disc space to the C7/T1 disc space for the treatment of cervical degenerative disc disease. Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history or radiographic studies. The device system is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and /or corticocancellous bone graft, to facilitate fusion. The device is implanted by an anterior approach. The TOMCAT™ implant must be used with the screws included in the TOMCAT™ system. This device is to be used in patients who have had six weeks of non-operative treatment.

VI. Comparison of Technological Characteristics with the Predicate Device

The device design remains unchanged from the original 510(k) submission (K152515).

VII. Performance Data

Sterilization validation performed in accordance with ISO 11137
Pyrogenicity testing performed in accordance with USP <85> Bacterial Endotoxin Test (BET) and ANSI/AAMI ST72.

VII. Conclusions

The purpose of this submission is to gain clearance for an additional method of sterilization for the TOMCAT™ Interbodies of the TOMCAT™ Cervical Spinal System. The indications for use and design characteristics of the system devices have not changed. Therefore, it can be concluded that the subject device is substantially equivalent to the predicate.