510(k) SUMMARY

I. SUBMITTER

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Establishment Registration: 3011181154

II. DEVICE

SUBJECT DEVICE

Trade Name: CancelleX Porous Titanium Lumbar Interbody System
Common Name: Intervertebral fusion device with bone graft, lumbar
Classification Name: Intervertebral body fusion device
Regulation: 21 CFR 888.3080
Device Class: Class II
Product Code: MAX
Review Panel: Orthopedic

PREDICATE DEVICES

Type	510(k) #	Trade Name	Manufacturer	Product Code
Primary	K180373	CancelleX Porous Titanium Lumbar	Xenco Medical,	MAX

Predicate		Interbody Device	LLC.	
Additional Predicates				
Predicate	K143158	Xenco Medical Lumbar Interbody System	Xenco Medical, LLC.	MAX
Predicate	K150481	Cascadia Interbody System	K2M	MAX
Predicate	K152011	Lucent XP Ti-Bond®	Spinal Elements, Inc.	MAX
Reference Predicates				
Reference	K102019	Restoration Acetabular Wedge Augments	Howmedica / Stryker Orthopedic	LPH

III. DEVICE DESCRIPTION

CancelleX Porous Titanium Lumbar Interbody System devices are being added to the Lumbar Interbody System. The CancelleX Porous Titanium Interbody devices are generally box shaped with surface teeth and a central channel for packing autogenous bone. These implants are available in a range of shapes and sizes to accommodate variations in patient anatomy. The devices are manufactured from Commercially Pure (Unalloyed) Titanium (ASTM F1580). The system also includes instruments manufactured using polyacrylamide (PARA-IXEF-GY51) polymer and stainless steel per ASTM F899.

IV. INDICATIONS FOR USE

CancelleX Porous Titanium Lumbar Interbody System devices are intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non- fusion spinal surgery at the involved spinal level(s). The device is intended to be used with supplemental fixation systems that have been cleared for use in the lumbrosacral spine (e.g. posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices (⩾20° lordosis) must be used with at least anterior supplemental fixation. The device is intended to be used with autogenous bone graft. Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the CancelleX device.

V. TECHNOLOGICAL CHARACTERISTICS

The subject device is substantially equivalent to the cited legally marketed predicate devices. The subject device has equivalent technological characteristics including design, materials, operating principle and indications for use.

VI. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing
Analysis was performed according to ISO 10993-1:2009 and biological effects were considered based on FDA Guidance, "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."

Bench Testing
Substantial equivalence of the CancelleX Porous Titanium Interbody Device was supported by evaluation for static and dynamic axial compression and compression shear testing per ASTM F2077 (Test Methods for Intervertebral Body Fusion Devices), subsidence testing per ASTM F2267 (Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression), and Expulsion testing.

Animal Study
Animal performance data was not required to determine substantial equivalence.

Clinical Studies
Clinical performance data was not required to determine substantial equivalence.

VII. CONCLUSIONS

Conclusions drawn from the non-clinical tests demonstrated that the subject device possessed at least equivalent performance characteristics as the predicate device, and that overall the subject device is substantially equivalent.