August 10, 2020

Stryker Corporation
Ms. Alexia Haralambous
Senior Staff Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K201585
Trade/Device Name: Monterey™ AL Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: June 10, 2020
Received: June 11, 2020

Dear Ms. Haralambous:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter, Ph.D.
Acting Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K201585

Device Name
Monterey™ AL Interbody System

Indications for Use *(Describe)*

Monterey™ AL Interbody System – Stand-Alone
The Stryker Spine Monterey™ AL Interbody System – Stand-Alone (AL Stand-Alone) is an interbody fusion device indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have six months of non-operative therapy.

Additionally, the Monterey™ AL Stand-Alone System can be used as adjunct to fusion in patients diagnosed with degenerative scoliosis.

The Monterey™ AL Stand-Alone System is intended to be implanted via an anterior approach.

The Monterey™ AL Stand-Alone System may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the Monterey™ AL Stand-Alone System must be used with the bone screws provided and requires no additional supplemental fixation. If Monterey™ AL Stand-Alone System is used with less than three or none of the provided bone screws, then additional supplemental fixation that has been cleared by the FDA for use in the lumbosacral spine must be used to augment stability. Hyperlordotic implants (>20° lordosis) are intended to be used with supplemental fixation (e.g., posterior fixation).

Monterey™ AL Interbody System – Spacer
The Stryker Spine Monterey™ AL Interbody System – Spacer (AL Spacer) is an intervertebral body fusion device indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have six months of non-operative therapy.

Additionally, the Monterey™ AL Spacer System can be used as adjunct to fusion in patients diagnosed with degenerative scoliosis.

The Monterey™ AL Spacer System is intended to be implanted via an anterior approach.

The Monterey™ AL Spacer System is intended to be used with supplemental fixation systems that have been cleared by the FDA for use in the lumbosacral spine.

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.**

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| 510(k) Summary: Monterey™ AL Interbody System | |
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| Manufacturer/Submitter: | Stryker Spine<br>2 Pearl Ct.<br>Allendale, NJ 07401 |
| Contact Person: | Name: Alexia Haralambous<br>Phone: (201) 749-8518<br>Email: alexia.haralambous@stryker.com |
| Date Prepared: | August 7, 2020 |
| Trade Name: | Monterey™ AL Interbody System |
| Common Name: | Intervertebral body fusion device |
| Proposed Class: | Class II |
| Classification Name: | Intervertebral Fusion Device with Integrated Fixation, Lumbar (21 CFR 888.3080)<br>Intervertebral Body Fusion Device with Bone Graft, Lumbar (21 CFR 888.3080) |
| Product Code: | OVD, MAX |
| Predicate Devices: | Primary Predicate:<br>▪ K2M *SAHARA Stabilization System* (K151481)<br><br>Additional Predicates:<br>▪ Stryker *AVS Anchor-L Lumbar Cage System* (K143163, K120869)<br>▪ Centinel Spine *STALIF TT* (K073109)<br>▪ Stryker *Tritanium® PL Posterior Lumbar Cage* (K181014, K160955, K152304)<br>▪ Stryker *Tritanium® TL Posterior Curved Lumbar Cage* (K173476)<br>▪ Stryker *Tritanium® X PL Expandable Posterior Lumbar Cage; Tritanium® X TL Expandable Curved Posterior Lumbar Cage* (K200613, K183249)<br>▪ Globus *Independence® Spacers* (K170157)<br>▪ Synthes *SYNFIX Evolution Secured Spacer System* (K150673)<br>▪ 4WEB *Anterior Spine Truss System – Stand Alone (ASTS-SA)* (K200002)<br>▪ Stryker *Tritanium® C Anterior Cervical Cage* (K171496) |
| Device Description: | The purpose of this Traditional 510(k) submission is to introduce the Monterey™ AL Interbody System, a new anterior lumbar interbody fusion device (IBD) product line.<br><br>These cages consist of a unique configuration of both solid and porous structures that are simultaneously built using Laser Rapid Manufacturing (LRM) method applying Stryker's proprietary Tritanium® In-Growth Technology. The cage has two designs: a stand-alone cage which includes screw holes for integrated fixation, and a spacer for use with external supplemental fixation. The cage is offered in a variety of heights, depths, widths, and lordotic angles to adapt to a variety of patient anatomies. It has serrations on the superior and inferior surfaces designed for multi-directional |

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| 510(k) Summary: Monterey™ AL Interbody System | |
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| | biological fixation and to maximize surface area for endplate contact with the implant. The subject cages are wedge-shaped, featuring a tapered posterior edge for ease of pre-positioning and insertion into the disc space. The cages also contain a large central space for graft containment, as well as 2 lateral windows for graft visualization.<br><br>The Monterey™ AL cages and screws are manufactured out of Ti6Al4V.<br>▪ Cages: Ti6Al4V (ASTM F1472, ISO 5832-3, ASTM F136)<br>▪ Screws: Ti6Al4V (ISO 5832-3, ASTM F136) |
| Indications for Use: | **Monterey™ AL Interbody System – Stand-Alone**<br>The Stryker Spine Monterey™ AL Interbody System – Stand-Alone (AL Stand-Alone) is an interbody fusion device indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1.<br><br>DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have six months of non-operative therapy.<br><br>Additionally, the Monterey™ AL Stand-Alone System can be used as adjunct to fusion in patients diagnosed with degenerative scoliosis.<br><br>The Monterey™ AL Stand-Alone System is intended to be implanted via an anterior approach.<br><br>The Monterey™ AL Stand-Alone System may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the Monterey™ AL Stand-Alone System must be used with the bone screws provided and requires no additional supplemental fixation. If Monterey™ AL Stand-Alone System is used with less than three or none of the provided bone screws, then additional supplemental fixation that has been cleared by the FDA for use in the lumbosacral spine must be used to augment stability. Hyperlordotic implants (>20° lordosis) are intended to be used with supplemental fixation (e.g., posterior fixation).<br><br>**Monterey™ AL Interbody System – Spacer**<br>The Stryker Spine Monterey™ AL Interbody System – Spacer (AL Spacer) is an intervertebral body fusion device indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. |

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| 510(k) Summary: Monterey™ AL Interbody System | |
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| | DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have six months of non-operative therapy.<br><br>Additionally, the Monterey™ AL Spacer System can be used as adjunct to fusion in patients diagnosed with degenerative scoliosis.<br><br>The Monterey™ AL Spacer System is intended to be implanted via an anterior approach.<br><br>The Monterey™ AL Spacer System is intended to be used with supplemental fixation systems that have been cleared by the FDA for use in the lumbosacral spine. |
| Summary of the Technological Characteristics | The subject Monterey™ AL Interbody System was demonstrated to be substantially equivalent to the identified predicate devices based on material, design features, fundamental scientific technology, and mechanical performance. |
| Summary of the Performance Data | Testing in accordance with FDA's June 12, 2007 "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the subject Monterey™ AL Cages and demonstrated substantially equivalent performance to the identified predicate devices. The following mechanical tests were performed:<br>• Static and Dynamic Compression (per ASTM F2077-18)<br>• Static and Dynamic Compression Shear (per ASTM F2077-18)<br>• Static Torsion (per ASTM F2077-18)<br>• Expulsion<br>• Subsidence (per ASTM F2267-04)<br>• Wear Particulate Analysis (per ASTM F1877-16)<br>• Impaction<br>• Screw Push Out<br>• Screw Pull Through |
| Conclusion | Based on the design features, the use of established well known materials, feature comparisons, indications for use, and results of the mechanical testing, the Monterey™ AL Cage has demonstrated substantial equivalence to the identified predicate devices. |