September 23, 2022

Acuity Surgical Devices, LLC
% Lucie Dalet, Ph.D.
Principal Consultant
RQM+
2251 San Diego Ave, B-257
San Diego, California 92110

Re: K222561
Trade/Device Name: Align
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: August 23, 2022
Received: August 24, 2022

Dear Dr. Dalet:

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.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K222561

Device Name
Align

Indications for Use *(Describe)*
Align anterior cages are indicated for intervertebral body fusion of the spine in skeletally mature patients who have had at least six months of non-operative treatment. The device systems are designed for use with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and/or autograft to facilitate fusion. One device is used per intervertebral body space. Align anterior cages are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
Align 2-screw anterior cages may be used as a stand alone device only when two (2) vertebral body bone screws are used. Align 4-screw anterior cages may be used as a stand alone device only when at least two (2) vertebral body bone screws are inserted in the two medial fixation holes with one inferior and one superior screw trajectory. If the physician chooses to use Align anterior cages with fewer than two (2) screws in the two medial fixation holes with one inferior and one superior screw trajectory, then an additional supplemental spinal fixation system cleared for use in the lumbosacral spine must be used.

Align anterolateral cages are indicated for intervertebral body fusion of the spine in skeletally mature patients who have had at least six months of non-operative treatment. The device systems are designed for use with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and/or autograft to facilitate fusion. One device is used per intervertebral body space. Align anterolateral cages are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Align anterolateral cages are intended to be used with supplemental spinal fixation system cleared for use in the lumbosacral spine.

Align lateral cages are indicated for intervertebral body fusion of the spine in skeletally mature patients who have had at least six months of non-operative treatment. The device systems are designed for use with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and/or autograft to facilitate fusion. One device is used per intervertebral body space. Align lateral cages are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Align lateral cages are intended to be used with supplemental spinal fixation system cleared 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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DATE PREPARED
August 23, 2022

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	Align
Common Name:	Intervertebral body fusion device
Regulation Number:	21 CFR 888.3080
Class:	II
Product Code:	OVD, MAX
Premarket Review:	Orthopedic Devices (OHT6)/Spinal Devices (DHT6B)
Review Panel:	Orthopedic

PREDICATE DEVICE IDENTIFICATION
Align is substantially equivalent to the following predicate:

510(k) Number	***Primary Predicate Device Name / Manufacturer***
K201671	A-Link Z / Acuity Surgical Devices, LLC

510(k) Number	***Reference Device Name / Manufacturer***
K201614	TxTiHA IBF System, AxTiHA Stand-Alone ALIF System / Innovasis, Inc.
K170392	S.I.N. Dental Implant System / S.I.N. - Sistema de Implante Nacional S.A.
K101225	Endosseous Implant and Abutment / Promimic AB
K130958	True Spinal Fixation System / Innovative Surgical Designs, Inc.

DEVICE DESCRIPTION
Align implants are intervertebral body fusion devices intended for lumbar interbody fusion using an anterior lumbar interbody fusion surgical approach (ALIF), anterolateral (i.e., oblique) lumbar interbody fusion surgical approach (OLIF), or a lateral lumbar interbody fusion surgical approach

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(LLIF). The devices are intended to improve stability of the spine while supporting fusion. The Align constructs are intended for use at one or two contiguous levels in the lumbar spine (L2-S1). Components are offered in different shapes and sizes to meet the requirements of the individual patient's anatomy and are provided sterile. Align devices are available in six configurations: modular constructs, standard constructs, fully round ALIF (FRA) constructs, and open constructs for ALIF approach, anterolateral (i.e., oblique) constructs for OLIF approach, and lateral constructs for LLIF approach. Align cages are secured on the vertebral bodies using bone screws. A cover plate assembly prevents the screws from backing out after insertion. The cages and cover plates are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F3001 Standard Specification for Additive Manufacturing Titanium-6 Alulminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion. The bone screws and cover plate screws are made from titanium alloy (Ti-6Al-4V ELI) per ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications. All constructs are zero profile, reducing potential for vessel interference with the anterior column. With the exception of the modular constructs, all cages and bone screws are also available with a hydroxyapatite coating.

INDICATIONS FOR USE

Align anterior cages are indicated for intervertebral body fusion of the spine in skeletally mature patients who have had at least six months of non-operative treatment. The device systems are designed for use with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and/or autograft to facilitate fusion. One device is used per intervertebral body space. Align anterior cages are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Align 2-screw anterior cages may be used as a stand alone device only when two (2) vertebral body bone screws are used. Align 4-screw anterior cages may be used as a stand alone device only when at least two (2) vertebral body bone screws are inserted in the two medial fixation holes with one inferior and one superior screw trajectory. If the physician chooses to use Align anterior cages with fewer than two (2) screws in the two medial fixation holes with one inferior and one superior screw trajectory, then an additional supplemental spinal fixation system cleared for use in the lumbosacral spine must be used.

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Align lateral cages are indicated for intervertebral body fusion of the spine in skeletally mature patients who have had at least six months of non-operative treatment. The device systems are designed for use with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and/or autograft to facilitate fusion. One device is used per intervertebral body space. Align lateral cages are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Align lateral cages are intended to be used with supplemental spinal fixation system cleared for use in the lumbosacral spine.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Acuity Surgical Devices believes that the Align is substantially equivalent to the predicate device based on the information summarized here:

The subject device has identical indications for use, design and dimensions, and uses identical materials as the device cleared in K201671. The subject device has identical or similar technological characteristics as the primary predicate device.

The main differences with the predicate device are the addition of a hydroxyapatite coating, the Promimic HA^{nano} Surface coating, on the unitary implants previously cleared in K201671, and the modification of the cover plate screw to include a break-off feature, which breaks away when the appropriate torque is reached. Design control activities, including validation testing of HA^{nano} Surface integrity per the Promimic protocol and validation testing of the break-off cover plate screws, were performed on the new version of the device to ensure the device is as safe and effective as the predicate.

SUMMARY OF NON-CLINICAL TESTING

- Performance testing per ASTM F2077 for Static Axial Compression, Dynamic Axial Compression, Static Compression Shear, Dynamic Compression Shear, and ASTM F2267 for Subsidence and Expulsion testing performed on the predicates applies to the modified devices because there is no difference in size, dimension, raw material or manufacturing method or equipment, with the exception of a nanometer thin layer of hydroxyapatite applied to the surface.

- Performance testing of HA^{nano} Surface integrity was conducted per the Promimic protocol, as accepted by FDA for the clearance of the reference devices K201614 (TxTiHA IBF System, AxTiHA Stand-Alone ALIF System, Innovasis, Inc.), K170392 (S.I.N. Dental Implant System, S.I.N), and K101225 (Endosseous Implant and Abutment, Promimic AB).

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- Performance testing of the break-off cover plate screw per the protocol accepted by FDA for the clearance of the reference device K130958 (True Spinal Fixation System, Innovative Surgical Designs, Inc.)

The results of these tests indicate that Align is substantially equivalent to the predicate and reference devices.

SUMMARY OF CLINICAL TESTING

No clinical data were provided to demonstrate substantial equivalence.

CONCLUSION

Based on the testing performed, including HA^{nano} Surface integrity testing and break-off cover plate screw performance testing, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The identical indications for use, technological characteristics, and performance characteristics of Align are assessed to be substantially equivalent to the predicate device.