July 10, 2025

Avalign Technologies, Inc.
Jennifer Staunton
Director Regulatory Affairs
8727 Clinton Park Drive
Fort Wayne, Indiana 46825

Re: K250072
Trade/Device Name: CONDUIT™ SYNFIX™ Evolution Secured Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: June 11, 2025
Received: June 11, 2025

Dear Jennifer Staunton:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250072

Device Name

CONDUIT™ SYNFIX™ Evolution Secured Spacer System

Indications for Use *(Describe)*

The CONDUIT™ SYNFIX™ Evolution Secured Spacer System is a stand-alone anterior interbody fusion device with a microscope roughened surface and micro and nano-scale features indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the spacer component of the CONDUIT SYNFIX Evolution can be packed with autograft. If used with less than the four integrated bone screws, or for hyperlordotic implants (>20Deg), implants must be used with supplemental fixation systems cleared by the FDA for use in the lumbosacral spine.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months 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.

510(k) Summary

Submitter:	Avalign Technologies, Inc. 8727 Clinton Park Drive Fort Wayne, IN 46825 USA
Contact Person:	Jennifer Staunton Director Regulatory Affairs Telephone: 219-718-1152
Date Prepared:	January 9, 2025
Trade Name:	CONDUIT™ SYNFIX™ Evolution Secured Spacer System
Device Class:	Class II
Product Code:	OVD, MAX
Common Name:	Intervertebral Fusion Device With Integrated Fixation, Lumbar
Classification Name:	Intervertebral Body Fusion Device
Regulation Number:	21 CFR 888.3080
Classification Panel:	Orthopaedic and Rehabilitation Devices Panel (87)
Primary Predicate:	Synthes SYNFIX™ Evolution Secured Spacer System (K150673)
Additional Predicates:	DePuy Synthes EIT Cellular Titanium® ALIF Cage (K201605) EIT Emerging Implant Technologies, GmbH Cellular Titanium® ALIF Cage (K170503) Stryker Monterey™ AL Interbody System (K201585)
Device Description:	The CONDUIT SYNFIX Evolution Secured Spacers are intervertebral body fusion devices intended for lumbar interbody fusion (ALIF). Four Screws are inserted through the anteriorly-located Plate into the adjacent vertebral bodies. The Screws lock securely to the Plate using a tapered-thread locking mechanism. The CONDUIT SYNFIX Evolution Secured Spacer System is available as non-assembled Cage and Plate components in various heights and geometries to suit individual pathology and anatomical conditions. The Cage and Plate components are intended to be assembled at the point of use prior to implantation. The CONDUIT SYNFIX Evolution Cages are made from Ti-6Al-4V

	ELI conforming to ASTM F3001 with an additive manufacturing process (Selective Laser Melting). The design contains solid structures and porous structures. The hollow geometry of the implants allows them to be packed with autogenous bone graft. The 3D Printed Conduit Cellular Titanium Cages have a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the Cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.
Indications for Use:	The CONDUIT™ SYNFIX™ Evolution Secured Spacer System is a stand-alone anterior interbody fusion device with a microscope roughened surface and micro and nano-scale features indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the spacer component of the CONDUIT SYNFIX Evolution can be packed with autograft. If used with less than the four integrated bone screws, or for hyperlordotic implants (>20Deg), implants must be used with supplemental fixation systems cleared by the FDA for use in the lumbosacral spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.
Materials:	The components are manufactured from medical grade Titanium. The Cage from standard specification for Ti-6Al-4V ELI using full-melt powder bed fusion in conformance with ASTM F3001. The Plate is manufactured from Ti-6Al-4V per ASTM F136 and bone Screws are supplied by DePuy Synthes and manufactured from Ti-6Al-7Nb (ISO 5832).
Comparison to Predicate Device:	The substantial equivalence of the subject device to the predicates identified above is based upon the equivalence of intended use, design (fundamental scientific technology), performance, sterility, and biocompatibility.
Performance Data:	Mechanical testing, including static and dynamic axial compression per ASTM F2077-24, static and dynamic compression shear per ASTM F2077-24, subsidence per ASTM F2267-24, and expulsion was performed to provide data to support a substantial equivalence

determination. The mechanical testing was performed to characterize the properties and functionality of the system, as well as to allow comparison with established acceptance criteria.

Additionally, the subject device was evaluated for magnetically induced displacement force per ASTM F2052-21, magnetically induced torque per ASTM F2213-17, MR image artifact per ASTM F2119-24 and RF-induced heating per ASTM F2182-19e2 to support the MR Conditional labeling.

Clinical Test Summary: No clinical data was necessary to demonstrate substantial equivalence, nor safety and effectiveness of this system.

Conclusion: Based on the predicate comparison of intended use, indications, technological characteristics, and device performance, the CONDUIT SYNFIX Evolution Secured Spacer System has demonstrated substantial equivalence to the identified predicate device systems.