October 28, 2026

Fziomed, Inc.
Lisa Gawehn
Director, Regulatory Affairs and Quality Assurance
231 Bonetti Dr.
San Luis Obispo, California 93401

Re: K262343
Trade/Device Name: Dynavisc
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWW
Dated: September 30, 2026
Received: September 30, 2026

Dear Lisa Gawehn:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262343

Please provide the device trade name(s).

Dynavisc

Please provide your Indications for Use below.

Dynavisc® Tendon Protector is indicated for the management and protection of longitudinal tendon injuries in which there has been no substantial loss of tendon tissue. The device may also be used to manage and protect surrounding tissues during the surgical procedure to treat these injuries, such as ligament and skeletal muscle. In these procedures, the device may encounter implanted structures such as anchors, grafts, staples, or sutures.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

510(k) Owner: Fziomed, Inc.
231 Bonetti Drive
San Luis Obispo, CA 93401
Contact: Paul Mraz
Phone: 805.549.7222
Date prepared: July 7, 2026

Device Name: Trade Name: Dynavisc®
Common Name: Tendon Protector
Classification Name: Mesh, Surgical
Regulation: 21 CFR §878.3300
Regulatory Classification: 2
Product Code: OWW

Predicate Device: K251655
VersaCoat Tendon Protector (VTP-44G2 and VTP-12G1)

Device Description:
Dynavisc® Tendon Protector (Dynavisc) is an absorbable, clear, flowable, viscoelastic gel that is comprised of sodium carboxymethylcellulose (CMC) and polyethylene oxide (PEO) along with calcium chloride and sodium chloride in sterile water for injection/irrigation. Dynavisc is single use, nonpyrogenic and contains no pharmaceutical agents, nor materials of human, animal, or bacterial origin. These components are combined to form an absorbable and viscous gel. Dynavisc was designed to coat soft tissue surfaces exposed during surgical repair to form a temporary physical barrier that protects the damaged tissue from the surrounding environment. Dynavisc does not provide mechanical support and has not been evaluated in repair of transverse tears or injuries. Apply only after the primary repair is complete and hemostasis is achieved.

Dynavisc is provided sterile in a capped syringe with a soft, flexible plastic applicator that features a smooth rounded tip designed to reduce the potential for tissue damage. The device is packaged in a thermoform tray with a Tyvek lid, then terminally sterilized, placed in a carton and labeled.

Indications for Use
Dynavisc® Tendon Protector is indicated for the management and protection of longitudinal tendon injuries in which there has been no substantial loss of tendon tissue. The device may also be used to manage and protect surrounding tissues during the surgical procedure to treat these injuries, such as ligament and skeletal muscle. In these procedures, the device may encounter implanted structures such as anchors, grafts, staples, or sutures.

Substantial Equivalence Comparison with the Predicate Device
Intended Use and Indications for Use are identical to the primary predicate device.

The mechanism of action, to manage tendon injuries, and surrounding tissue such as ligament and skeletal muscle, by providing a gliding surface and by keeping damaged tissues physically separated during healing, is identical between the subject device and the predicate.

The subject device and predicate are both applied as a single use sterile gel directly to the target site/tissue with no sutures or glue needed.

Differences between Dynavisc and the subject device (implant material and need for predicate need for rehydration prior to use) were determined to be minor and determined to not raise any different questions of safety or effectiveness.

Therefore, the criteria for a substantial equivalence determination have been met.

Functional and Safety Testing
To verify that device design met functional and performance requirements, bench testing of final, finished device samples was performed in accordance with applicable standards and FDA guidance. Data provide a reasonable assurance of the safety and effectiveness of Dynavisc Tendon Protector and demonstrate that the device is equivalent to the predicate. Biocompatibility evaluations have been conducted based on the type and duration of contact based on ISO 10993-1: 2018. All tests passed their respective ISO test expectations demonstrating that all components of Dynavisc are associated with low risk for inducing toxicity during their intended clinical use.

Non-Clinical and/or Clinical Test Summary and Conclusions
Clinical testing was not required to demonstrate substantial equivalence of Dynavisc to the predicate device. The following non-clinical tests were performed to support substantial equivalence:

Bench Performance Testing:
- *Rheology*
- *Homogeneity*
- *Swelling*
- *Aldehydes and EO*
- *USP 661 Testing*

Pre-Clinical Testing:
- *Evaluation of Local Tissue Response to Dynavisc in a Calcaneal Tendon Injury Model in Rabbits*

Biocompatibility Testing:
- *Cytotoxicity (ISO 10993-5)*
- *Sensitization (ISO 10993-10)*
- *Irritation (ISO 10993-23)*
- *Material Mediated Pyrogenicity (ISO 10993-11)*
- *Acute Systemic Toxicity (ISO 10993-11)*
- *Genotoxicity (ISO 10993-3)*
- *Subchronic Systemic Toxicity (ISO 10993-11)*
- *Intramuscular Implantation (ISO 10993-6)*
- *Systemic Toxicity (ISO 10993-11)*

Conclusion

The intended use, and key technological characteristics of the Dynavisc® Tendon Protector are substantially equivalent to the VersaCoat® (K251655) predicate device. Where there are differences, these have been determined to be minor and do not raise any different questions of safety or effectiveness. The non-clinical data provided supports the substantial equivalence of the Dynavisc® Tendon Protector to the predicate device.