December 23, 2024

Fusion Orthopedics
Catalina Pardo
Quality Engineer
6859 E Rembrandt Ave Suite 122
Mesa, Arizona 85212

Re: K242091
Trade/Device Name: Bolo Button System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN
Dated: December 3, 2024
Received: December 3, 2024

Dear Catalina Pardo:

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,

RYAN TROMBETTA -S

Digitally signed by RYAN TROMBETTA -S
Date: 2024.12.23 13:08:16 -05'00'

For: Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty 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: 0MB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242091

Device Name

Bolo Button System

Indications for Use *(Describe)*

The Bolo Button System is intended to provide fixation as an adjunct to fracture repair hardware during the healing period following an anklle syndesmotic trauma with fracture.

Type of Use *(Select one or both, as applicable)*

IXI Prescription Use (Part 21 CFR 801 Subpart D) D Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid 0MB number."

510(k) Summary: Bolo Button System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	December 19th, 2024
Submitted By	Fusion Orthopedics USA, LLC 6859 E. Rembrandt Ave., Suite 122 Mesa, AZ 85212 800-403-6876
Primary Contact	Eli Jacobson 6859 E. Rembrandt Ave., Suite 122 Mesa, AZ 85212 800-403-6876 Tele e-mail: eli@fusionorthopedics.com
Trade Name	Bolo Button System
Common Name	Soft Tissue Fixation Device
Class	II
Product Code	HTN
Regulation	21 CFR Section 888.3030 – Single/multiple component metallic bone fixation appliances and accessories.
Device Panel	Orthopedic
Predicate Devices	**Primary Predicate:** Smith & Nephew, Inc : INVISIKNOT Ankle Syndesmosis Repair Kit (K162996) **Additional Predicates:** Arthrex, Inc.: TightRope™ II (K202581) Zimmer Biomet, Inc.: ZipTight™ Ankle Fixation System (K130033) **Reference Device:** Fusion Orthopedics USA, LLC: PolyLock Plating System (K211843)
Device Description	The Bolo Button System consists of two syndesmosis buttons made of titanium alloy (Ti6Al4V ELI (ASTM F136)) and suture tape (Ultra High Molecular Weight Polyethylene Suture (UHMWPE) (ASTM F2848)). It is intended for fixation of syndesmotic injuries in an ankle fracture. The system offers two lateral button sizes. One fits 1.5mm suture tape and the other fits 2.0mm suture tape. Both share the same medial button. System instrumentation includes: drill bits, K-wires, tissue protector, and an inserter which deploys the implants. The implants and associated instrumentation are supplied sterile. This is a single use system.
Indications for Use	The Bolo Button System is intended to provide fixation as an adjunct to fracture repair hardware during the healing period following an ankle syndesmotic trauma with fracture.
Materials	Titanium Alloy Ti6Al4V ELI (ASTM F136) Stainless Steel (ASTM F899) Ultra-High Molecular Weight Polyethylene Suture (UHMWPE) (ASTM F2848)

Comparison of Technological Characteristics	The Bolo Button System and the predicate devices implants' are manufactured from titanium alloy (ASTM F136) are compatible with similar sized buttons, have similar widths, thickness, lengths, and designs/shapes. The suture tape which binds both buttons in the Bolo Button System is also used in the predicate device. Systems are equivalent in their features and in intended use.
Non-clinical Test Summary	Validations were performed on the cleaning, packaging and sterilization of the implants and associated surgical instruments. Engineering rational along with static and dynamic testing was performed to show substantial performance equivalence. The results of the testing demonstrate that the device is substantially equivalent to the predicate device identified above.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non- clinical and Clinical	Fusion Orthopedics USA, LLC considers the Bolo Button System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials, and indications for use.