November 21, 2025

Joint Preservation Innovations, LLC
% Rob Packard
Regulatory Consultant
Medical Device Academy
345 Lincoln Hill Road
Shrewsbury, Vermont 05738

Re: K252666
Trade/Device Name: Articulator Arthroscopic Bur
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: August 18, 2025
Received: August 25, 2025

Dear Rob Packard:

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,

Robert M. Stefani -S

Digitally signed by Robert M. Stefani -S
Date: 2025.11.21 14:37:13 -05'00'

For: Jesse Muir, Ph.D.
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.	K252666

Please provide the device trade name(s).

Articulator Arthroscopic Bur

Please provide your Indications for Use below.

The Articulator™ Arthroscopic Bur is indicated for use in orthopedic and arthroscopic procedures for the following joints: knee, shoulder, ankle, elbow, wrist, and hip, to provide abrasion, resection, debridement, and removal of bone and cartilage.

Please select the types of uses (select one or both, as applicable).

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

510(k) SUMMARY
K252666

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92(a):

I. SUBMITTER

Company Name: Joint Preservation Innovations, LLC
Contact Person: Mr. Sanjeev Bhatia, MD
Address: 115 E. Ogden Ave., Suite 105-323
Naperville IL 60563 USA
Tel: +1.312.404.4903

Submission Contact: Rob Packard, Regulatory Consultant
Medical Device Academy, Inc.
Tel: +1.802.258.1881
rob@fdaestar.com

Date Prepared: October 21, 2025

II. DEVICE

Device Trade Name:	Articulator Arthroscopic Bur
Classification Name:	Arthroscope
Regulation:	21 CFR 888.1100
Regulatory Class:	Class II
Device Panel:	Orthopedics
Product Classification Code:	HRX

III. PREDICATE DEVICE

Primary Predicate Manufacturer:	Stryker Endoscopy
Primary Predicate Trade Name:	Stryker Crossfire System
Primary Predicate 510(k):	K071859
Secondary Predicate Manufacturer:	LivsMed Inc.
Secondary Predicate Trade Name:	ArtiSential Laparoscopic Instruments - Electrodes
Secondary Predicate 510(k):	K200875

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Articulator Arthroscopic Bur can be used to abrade, cut and excise tissue and bone in arthroscopic surgeries.

The arthroscopic bur components include a bur attached to a constant velocity joint that is attached to a long rod rotating within a long hollow stainless steel housing. The bur is shielded on

one side by its housing, allowing the bur to cut one structure while tissues on the opposite side of the shield are protected. A pushrod stabilizes the burr housing and holds the articulation into one of three preset flexion angles chosen by the user. A trigger mechanism on the proximal end of the bur allows the user to ergonomically flex and release the working angle of the bur with one hand. This system attaches to a motorized handpiece that drives the internal bur inside the outer housing and provides suction to pull the cut tissue away from the surgical site.

V. INDICATIONS FOR USE

The Articulator™ Arthroscopic Bur is indicated for use in orthopedic and arthroscopic procedures for the following joints: knee, shoulder, ankle, elbow, wrist, and hip, to provide abrasion, resection, debridement, and removal of bone and cartilage.

- Indications for Use Comparison – The subject device and the Crossfire system match with regard to indications in the first sentence. However, the subject device does not include shaver blades or bipolar electrosurgical instruments. Therefore, those elements and the associated indications are not included in the subject device indications.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device:

- Technological Difference Comparison – The subject device differs from the Crossfire system in that it does not have a shaver blade or bipolar electrosurgical instruments and because the subject device has articulation, which the Crossfire system does not.

  The articulation portion of the ArtiSential device is similar to the subject device, but the subject device does not include electrosurgical functions. The articulating features of the subject device raise the same issues of risk as the ArtiSential device.

  The elimination of electrosurgical functions eliminates risks associated with those functions. Nonclinical testing was completed to demonstrate that differences in the technological characteristics do not present new or different issues of risk when compared with the Crossfire system or the ArtiSential device.

SE Comparison Table

Table 1: Comparison of Subject Device, Articulator Arthroscopic Bur (K252666) with the Primary Predicate Device, Stryker Crossfire System (K071859)

	Articulator Arthroscopic Bur Subject Device (K252666)	1° Predicate Device Stryker Crossfire System (K071859)	Justification for differences
Indications for Use	The Articulator™ Arthroscopic Bur is indicated for use in orthopedic and arthroscopic procedures for the following joints: knee, shoulder, ankle, elbow, wrist, and hip, to provide abrasion, resection, debridement, and removal of bone and cartilage.	The Stryker Crossfire System is intended for use in orthopedic and arthroscopic procedures for the following joints: knee, shoulder, ankle, elbow, wrist, and hip. The Crossfire System provides abrasion, resection, debridement and removal of bone and soft tissue through its shaver blade; and the ablation and coagulation of soft tissue, as well as hemostasis of blood vessels, through its electrosurgical probe. Examples of uses of the product include resection of torn knee cartilage, subacromial decompression, and resection of synovial tissue in other joints.	The subject device the Crossfire system match with regard to indications in the first sentence. However, the subject device does not include shaver blades or bipolar electrosurgical instruments. Therefore, those elements and the associated indications are no included in the subject device indications.
Manufacturer	Joint Preservation Innovations, LLC	Stryker Endoscopy	N/A
Classification	Class 2	Class 2	Same
Rx-only/OTC	Rx-only	Rx-only	Same
Principles of Operation	The bur is comprised of hardened 440c stainless steel with an abrasive cutting surface that rotates with a protective hood to grind down bone or cartilage. An arthroscopic irrigation solution, such as normal saline or lactated ringers solution, is needed when using the device to irrigate regularly throughout the procedure, and suction is used to clear the surgical field of irrigant and debris. Traditionally,	The predicate device uses a powered handpiece to activate the shaver blade and bipolar energy for ablation and coagulation with the RF probe.	The subject device has lower energy and reduced risk when compared to the predicate with RF power.

	arthroscopic burs are introduced into the body under direct visual or endoscopic guidance, ensuring that the tip of the bur is carefully inserted into the desired location.		
Energy Type	Stryker Crossfire Arthroscopy Console (electromechanical)	Radiofrequency	The subject device and the predicate have the same energy source for the non-RF functions. Specifically, the Stryker Crossfire system is the power console that powers the handpiece of the subject device.
Monopolar/Bipolar	N/A	Bipolar	The subject device does not include electrosurgical functions.
Physical Dimensions	• Shaft diameter: 6.35 mm • Shaft length: 205 mm	• Shaft diameter: 7.18 mm • Shaft length: 127 mm	The longer length of the shaft of the subject device was demonstrated to be equivalent in performance testing. The slightly smaller diameter of the subject device increases versatility, and performance testing demonstrated that performance testing was not negatively impacted.
Rated Voltage	N/A	400V	The subject device does not include electrosurgical functions.
Materials (electrode)	N/A	Tungsten	The subject device does not include electrosurgical functions.
Materials (insulation)	N/A	Ceramic	The subject device does not include electrosurgical functions.
Materials (shaft)	PEEK	Stainless steel	Both the subject device and the ArtiSential device meet the requirements of recognized biocompatibility standards.
Bone Bur	• Diameter = 5.3 mm • Number of flutes = 9 • Material = Stainless steel	• Diameter = 5.5 mm • Number of flutes = 12 • Material = Stainless steel	Equivalence of the slightly different bone bur specifications was demonstrated during performance testing.
Articulating Feature	Pitch: 0 to -30°	None	Risks associated with

			articulation are addressed by benchtop top
Maximum RPM	12,000	12,000	Same
Oscillate maximum RPM	3,000	3,000	Same
Motor peak torque	1.4in*lbs.	1.4in*lbs.	Same
Sterilization Method	Gamma	EO	Both the subject device and the Crossfire device meet the requirements of recognized sterilization validation standards.
Reusable/Disposable	Disposable	Reusable	The subject device is lower risk because it is not reusable.

Table 2: Comparison of Subject Device, Articulator Arthroscopic Bur (K252666) with the Secondary Predicate Device, ArtiSential Laparoscopic Instruments-Electrodes (K200875)

	Articulator Arthroscopic Bur Subject Device (K252666)	2° Predicate Device ArtiSential Laparoscopic Instruments-Electrodes (K200875)	Justification for differences
Description/ Indications	The Articulator Arthroscopic Bur is an accessory to a powered arthroscopic handpiece and is intended for use in orthopedic and arthroscopic procedures for the following joints: knee, shoulder, ankle, elbow, wrist, and hip, to provide abrasion, resection, debridement, and removal of bone and cartilage. Examples of uses of the product include resection of bone in hip arthroscopy for femoroacetabular impingement, shoulder arthroscopy for subacromial impingement and distal clavicle resection.	Electrosurgical coagulation, dissection, and grasping of tissue during the performance of laparoscopic and general surgical procedures.	The articulation portion of the ArtiSential device is similar to the subject device, but the subject device does not include electrosurgical functions. The articulating features of the subject device raise the same issues of risk as the ArtiSential device.
Manufacturer	Joint Preservation Innovations, LLC	LivsMed, Inc.	N/A
Classification	Class 2	Class 2	Same
Rx-only/OTC	Rx-only	Rx-only	Same

Principles of Operation	The bur is comprised of hardened 440c stainless steel with an abrasive cutting surface that rotates with a protective hood to grind down bone or cartilage. An arthroscopic irrigation solution, such as normal saline or lactated ringers solution, is needed when using the device to irrigate regularly throughout the procedure, and suction is used to clear the surgical field of irrigant and debris. Traditionally, arthroscopic burs are introduced into the body under direct visual or endoscopic guidance, ensuring that the tip of the bur is carefully inserted into the desired location.	This product is a single-use instrument used in electrosurgical units to hold soft tissues or coagulate and make an incision (tissue dissection) during general laparoscopic surgery, which uses the principle of applying high frequency currents from the electrode to the human body to generate heat by bioimpedance when radio frequency (RF) energy from the electrosurgical unit applies an electric current to the electrode part, and using the generated heat to incise cellular tissues and cause coagulation. It is composed of a jaw, Φ8 diameter shaft, grip (including a control ring), and electrosurgical unit connection electrode connector. During a procedure with this product, the jaw opens if the control ring opens, and jaw closes if the control ring closes. In addition, the jaw is also bent up, down, left and right within a range of ±80° or more by moving the grip up, down, left and right, and the jaw can	Equivalent with regard to mechanical bone cutting functions and articulation.

		also turn 360° when rotating the grip.	
Energy Type	Stryker Crossfire Arthroscopy Console (electromechanical)	Radiofrequency	The subject device has lower energy and reduced risk when compared to the predicate with RF power.
Monopolar/Bipolar	N/A	Bipolar	The subject device does not include electrosurgical functions.
Physical Dimensions	• Shaft diameter: 6.35 mm • Shaft length: 205 mm	• Shaft diameter: 8 mm • Shaft length: 250 mm, 380 mm, 450 mm	The slightly shorter length of the shaft of the subject device was demonstrated to be equivalent in performance testing. The slightly smaller diameter of the subject device increases versatility, and performance testing demonstrated that performance testing was not negatively impacted.
Rated Voltage	N/A	200Vp	The subject device does not include electrosurgical functions.
Materials (electrode)	N/A	Stainless steel	The subject device does not include electrosurgical functions.
Materials (insulation)	N/A	Polyetherimide	The subject device does not include electrosurgical functions.
Materials (shaft)	PEEK	Glass fiber	Both the subject device and the ArtiSential device meet the requirements of recognized biocompatibility standards.
Articulating Feature	• Pitch: 0 to -30°	• Pitch: ±80° or more	The subject device does not have as great

		• Yaw: ±80° or more and Open-Close	of a range of motion with regard to pitch as the ArtSential device, but the shaft can be rotated manually. The subject device has no articulation with regard to Yaw. The reduced articulation reduces risk of malfunction.
Tip Rotation	360°	360°	Same
Sterilization Method	Gamma	EO	Both the subject device and the ArtiSential device meet the requirements of recognized sterilization validation standards.
Reusable/Disposable	Disposable	Disposable	Same

VII. PERFORMANCE DATA

The following performance data were provided and met acceptance criteria:

Biocompatibility Testing

• Cytotoxicity Testing (MEM Elution) - ISO 10933-5
• Sensitization Testing (Guinea Pig Maximization) - ISO 10933-10
• Irritation Testing (Intracutaneous Irritation) - ISO 10933-23
• Acute Systemic Toxicity - ISO 10993-11
• USP <151> Material Mediated Pyrogenicity testing

Sterilization Validation

• ISO 11137-1 Requirements for development validation and routine control of a sterilization process for medical devices
• ISO 11137-2 Establishing the sterilization dose
• ANSI/ASTM ST72 & USP-NF<85> Bacterial Endotoxin testing

Shelf-Life

• ASTM F1980-21 Accelerated Aging

Packaging Validation
• ISO 11607-1
• ISO 11607-2
• ASTM D4169-22

Electrical safety and electromagnetic compatibility (EMC)
Not required for this submission.

Software Verification and Validation Testing
Not required for this submission.

Non-Clinical Benchtop Testing
• Cutting efficiency
• Surface temperature
• Articulation mechanism strength

Animal Performance Testing
Not required for this submission.

Human Clinical Testing
Not required for this submission.

VIII. CONCLUSIONS
The subject device, Articulator Arthroscopic Bur, has the same indications for use when compared with the primary predicates arthroscopic bur indications for use (i.e., Stryker Crossfire System K071859), but the subject device does not include bipolar electrosurgical indications.

A secondary predicate device/reference device (i.e., ArtiSential Laparoscopic Instruments K200875) were used for comparison with the technological differences of the articulation feature of the subject device.

Non-clinical benchtop testing shows that the subject device is substantially equivalent in terms of safety and effectiveness when compared with the predicate devices and performs as well as the predicates.