December 11, 2023

ArthroCare Corporation
Jennifer Burns
Regulatory Affairs Specialist II
7000 West William Cannon Drive
Austin, Texas 78735

Re: K232290
Trade/Device Name: INTELLIO SHIFT System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, HRX
Dated: November 13, 2023
Received: November 14, 2023

Dear Jennifer Burns:

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.

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.12.11 15:28:16 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232290

Device Name
INTELLIO SHIFT System

Indications for Use *(Describe)*
The INTELLIO SHIFT System is indicated for:
-Resection of soft and osseous tissues
-Resection, Ablation and Coagulation of soft tissue and hemostasis of blood vessels during the following arthroscopic and orthopedic procedures:

•Articular Cartilage
•Bursectomy
•Chondroplasty
•Fascia
•Ligament
•Scar Tissue
•Soft Tissue
•Synovectomy
•Tendon
•Articular Labrum
•Capsule
•Cysts
•Ligament
•Loose Bodies
•Plica Removal
•Scar Tissue
•Soft Tissue
•Synovial Membrane
•Tendon
•Acetabular Labrum
•ACL/PCL
•Notchplasty
•Capsular Release
•Cartilage Flaps
•Discoid Meniscus
•Lateral Release
•Meniscal Cystectomy
•Meniscectomy
•Villusectomy
•Acromioplasty
•Subacromial Decompression
•Frozen Shoulder Release
•Glenoid Labrum
•Triangular Fibrocartilage (TFCC)
•Hemostasis (via Coagulation) of soft tissue and bone

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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INTELLIO SHIFT
SMITH AND NEPHEW INC.
K232290

510K SUMMARY

Pursuant to Title 21 of Code of Federal Regulations, Subchapter H, section 807.92(a), the Traditional 510K Summary to seek clearance for the device INTELLIO SHIFT System is stated as follows:

1) **Submitter**: ArthroCare Corporation (a division of Smith and Nephew Inc.)
   Address: 7000 West William Cannon Drive, Austin, TX 78735-8531 USA
   Contact Person: Jennifer Burns
   Email: Jennifer.Burns@smith-nephew.com
   Date: December 8, 2023

2) **Device:** INTELLIO SHIFT System
   Trade Name and/or Proprietary Name: INTELLIO SHIFT System
   Primary Regulation and Product Code: 878.440, GEI
   Reference Regulation and Product Code: 888.1100, HRX

3) **Primary Predicate Device:** WEREWOLF+ COBLATION System
   The INTELLIO SHIFT System is substantially equivalent to the WEREWOLF+ COBLATION System, cleared by the FDA under the Premarket Notification K210423.

4) **Reference Predicate Device:** DYONICS POWER II Control System
   The INTELLIO SHIFT System is substantially equivalent to the DYONICS POWER II Control System, cleared by the FDA under the Premarket Notification K062849.

5) **Intended Use of INTELLIO SHIFT System**

The INTELLIO SHIFT System is intended for:

- Resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in arthroscopic and orthopedic procedures.
- Hemostasis (via coagulation) of soft tissue and bone in joint arthroplasty procedures.
- Resection of soft and osseous tissues including, but not limited to, use in large articular cavities and small articular cavities

6) Indications for Use of INTELLIO SHIFT System

The INTELLIO SHIFT System is indicated for:

- Resection of soft and osseous tissues
- Resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels during the following arthroscopic and orthopedic procedures:

Arthroscopic		
Location	**Ablation/Debridement**	**Excision/Resection**
All Joints (Hip, Knee, Shoulder, Wrist, Ankle, Elbow)	• Articular Cartilage • Bursectomy • Chondroplasty • Fascia • Ligament • Scar Tissue • Soft Tissue • Synovectomy • Tendon	• Articular Labrum • Capsule • Cysts • Ligament • Loose Bodies • Plica Removal • Scar Tissue • Soft Tissue • Synovial Membrane • Tendon
Hip	N/A	• Acetabular Labrum
Knee	• ACL/PCL • Notchplasty	• Capsular Release • Cartilage Flaps • Discoid Meniscus • Lateral Release • Meniscal Cystectomy • Meniscectomy • Villusectomy
Shoulder	• Subacromial Decompression • Acromioplasty	• Frozen Shoulder Release • Glenoid Labrum
Wrist	N/A	• Triangular Fibrocartilage • (TFCC)
Orthopedic		
Hemostasis (via coagulation) of soft tissue and bone		

7) **Device Description Summary:** The INTELLIO SHIFT System combines two previously cleared technologies into one system. The INTELLIO SHIFT System is composed of (1) a controller that combines the radio frequency coblation/coagulation technology of the previously cleared (K210423) WEREWOLF+ COBLATION System with the mechanical resection technology of the previously cleared (K062849) DYONICS POWER II Control System and (2) a wired foot pedal that controls these two technologies. The INTELLIO SHIFT System utilizes the same technologies as the predicates and matches the performance requirements of the WEREWOLF+ and DYONICS POWER II controllers. The INTELLIO SHIFT System allows the user to select and operate two established resection technologies using the same device: Mechanical Resection (MR) for cutting and tissue removal, and Bipolar Radio Frequency (RF) for coblation/coagulation. The INTELLIO SHIFT System is compatible with various accessories including RF coblation/coagulation Wands, a Mechanical Resection Motor Drive Unit Handpiece, and a wired foot pedal. The INTELLIO SHIFT System interfaces with a handpiece Motor Drive Unit (MDU) shaver, to provide mechanical cutting and tissue removal. The INTELLIO SHIFT System interfaces with RF Wands to utilize bipolar RF technology for the resection, ablation, and coagulation of tissues and hemostasis of blood vessels in various arthroscopic, and orthopedic procedures. Additionally, the INTELLIO SHIFT System can be interfaced directly with 510K cleared fluid management systems. INTELLIO SHIFT provides an optional interface for the INTELLIO Connected Tower, which is composed of Smith and Nephew equipment typically used in arthroscopic or orthopedic surgical procedures and stored near each other on a single cart. While the INTELLIO SHIFT System provides options to healthcare professionals to use both Mechanical Resection and Coblation/Coagulation through the same device and within the same surgery, these technologies cannot be used at the exact same time.

8) Similarities between the subject and predicate devices:

- The functionality of providing Mechanical Resection, Radio Frequency Ablation, and Radio Frequency Coagulation is equivalent to the predicate devices.
- The hardware design of the subject device is similar to the combination of the predicate devices.
- The subject device is non-sterile, non-patient contacting, and intended for multi-patient use, which is equivalent to the predicate devices.
- The following electrical parameters are similar to the predicate devices.
- There are no changes to the accessories that have been previously cleared with the predicate devices.

9) Differences between the subject and the predicate devices:

- The subject device combines two cleared technologies already on the market as two separate devices into one system.
- The Intended Use and Indications for Use of the predicate devices have been combined for the subject device.
- A single Foot Pedal controls the functionality, whereas predicate devices each had a separate Foot Pedal.
- GUI display has been updated to combine functionality and the layout has been revised to improve ease of use.

10) Substantial Equivalence Table

Parameter	**PRIMARY PREDICATE DEVICE (K210423)**: WEREWOLF+ COBLATION System	**SUBJECT DEVICE**: INTELLIO SHIFT System	**REFERENCE PREDICATE DEVICE (K062849):** DYONICS POWER II Control System	**Rationale for Differences**
Intended Use	The **WEREWOLF+ COBLATION System** with compatible wands is intended for: Resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in arthroscopic, orthopedic and otorhinolaryngology (ENT) procedures.	The **INTELLIO SHIFT System** is intended for: •Resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in arthroscopic and orthopedic procedures. •Hemostasis (via coagulation) of soft tissue and bone in joint arthroplasty procedures. •Resection of soft and osseous tissues including, but not limited to, use in large articular cavities and small articular cavities	The **DYONICS POWER II Control System** is intended for use when used with appropriate procedure-specific blades, for resection of soft and osseous tissues including, but not limited to, use in large articular cavities, small articular cavities, and for functional endoscopic sinus surgery (FESS). The FESS application is limited to small blades that are appropriate for the procedure.	Based on the Intended Use of the primary predicate and the reference predicate, the subject device is substantially equivalent.
Indications for Use	The **WEREWOLF+ COBLATION System** controller is indicated for the resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in the following arthroscopic, orthopedic and otorhinolaryngology (ENT) procedures: • Articular Cartilage • Bursectomy • Chondroplasty • Fascia • Ligament • Scar Tissue • Soft Tissue • Synovectomy • Tendon • Articular Labrum	The **INTELLIO SHIFT System** is indicated for: •Resection of soft and osseous tissues •Hemostasis (via coagulation) of soft tissues and bone in joint replacement arthroplasty procedures •Resection, ablation and coagulation of soft tissue and hemostasis of blood vessels during the following arthroscopic and orthopedic procedures: •Articular Cartilage •Bursectomy •Chondroplasty •Fascia •Ligament •Scar Tissue •Soft Tissue •Synovectomy •Tendon •Articular Labrum •Capsule	The **DYONICS POWER II Control System** is indicated use when used with appropriate procedure-specific blades, for resection of soft and osseous tissues including, but not limited to, use in large articular cavities, small articular cavities, and for functional endoscopic sinus surgery (FESS). The FESS application is limited to small blades that are appropriate for the procedure.	Based on the Indications for Use of the primary predicate and the reference predicate, the subject device is substantially equivalent.

	• Capsule • Cysts • Ligament • Loose Bodies • Plica Removal • Scar Tissue • Soft Tissue • Synovial Membrane • Tendon • Acetabular Labrum • ACL/PCL • Notchplasty • Capsular Release • Cartilage Flaps • Discoid Meniscus • Lateral Release • Meniscal Cystectomy • Meniscectomy • Villusectomy • Acromioplasty • Subacromial Decompression • Frozen Shoulder Release • Glenoid Labrum • Triangular Fibrocartilage (TFCC) • Tonsillectomy (including Palatine Tonsils) Tracheal • Adenoidectomy • Uvulopalatopharyngoplasty (UPPP) • Traditional Uvulopalatoplasty Control (RAUP) • Nasal Airway Obstruction • Submucosal Palatal Shrinkage • Submucosal Tissue Shrinkage • Nasal Airway Obstruction by reduction of Hypertrophic Nasal Turbinates • Reduction of Turbinates for the treatment of Nasal Airway Obstruction • Nasopharyngeal/Laryngeal indications including Tracheal Procedures • Papilloma	•Cysts •Ligament •Loose Bodies •Plica Removal •Scar Tissue •Soft Tissue •Synovial Membrane •Tendon •Acetabular Labrum •ACL/PCL •Notchplasty •Capsular Release •Cartilage Flaps •Discoid Meniscus •Lateral Release •Meniscal Cystectomy •Meniscectomy •Villusectomy •Acromioplasty •Subacromial Decompression •Frozen Shoulder Release •Glenoid Labrum •Triangular Fibrocartilage (TFCC)		

	• Keloids • Nasopharyngeal/Laryngeal Procedures • Polypectomy • Laryngeal Polypectomy • Laryngeal Lesion Debulking • Cysts • Tumors • Neck Mass • Head, Neck, Oral, and Sinus Surgery • Tissue in the Uvula/Soft Palate for the treatment of snoring • Hemostasis (via coagulation) of soft tissue and bone			

General Device Characteristics				
Parameter	**PRIMARY PREDICATE DEVICE (K210423)**: WEREWOLF+ COBLATION System	**SUBJECT DEVICE**: INTELLIO SHIFT System	**REFERENCE PREDICATE DEVICE (K062849):** DYONICS POWER II Control System	**Rationale for Differences**
Functionality	Radiofrequency Resection, Ablation, Coagulation	Radiofrequency Resection, Ablation, Coagulation, Mechanical Resection (MR)	Mechanical Resection (MR)	Based on the functionality of the primary predicate and the reference predicate, the subject device is substantially equivalent.
Weight	22.1 lbs	30 lbs	13.85 lbs	Based on the weight of the primary predicate, the subject device is substantially equivalent.
Sterilization	Non-sterile	Non-sterile	Non-sterile	Equivalent

Device Usage	Multi-patient use Non-patient contacting	Multi-patient use Non-patient contacting	Multi-patient use Non-patient contacting	Equivalent
Prescription (Rx) / Over the Counter (OTC)	Prescription (Rx)	Prescription (Rx)	Prescription (Rx)	Equivalent
Foot Pedal Functions	Ablate/Coag/Vac/Mode selection	Ablate/Coag/Vac/Mode selection Forward/Reverse/Oscillate Lavage (DYONICS 25 Pump) Lavage and rinse (DOUBLE FLO Pump) Cycle Devices	Forward/Reverse/Oscillate Lavage (DYONICS 25 Pump) Lavage and rinse (DOUBLE FLO Pump)	Equivalent
Technical Specifications				
Parameter	**PRIMARY PREDICATE DEVICE (K210423)**: WEREWOLF+ COBLATION System	**SUBJECT DEVICE**: INTELLIO SHIFT System	**REFERENCE PREDICATE DEVICE (K062849):** DYONICS POWER II Control System	**Rationale for Differences**
Maximum Output Power	400 W	400 W	N/A because the DYONICS II System is not a RF device.	Equivalent
Maximum Output Voltage	680V	680V	N/A because the DYONICS II System is not a RF device.	Equivalent
Activation Indication	Audio and Visual (RF function)	Audio and Visual (RF function) Visual (MR function)	Visual (MR function)	Equivalent

Setting Adjustment Interface	Graphical User Interface (GUI) with digital buttons	Graphical User Interface (GUI) with digital buttons	Graphical User Interface (GUI) with digital buttons	Equivalent

11) Non-Clinical Performance Data: The following non-clinical tests were submitted and relied on in this premarket notification submission for a determination of substantial equivalence. Testing identified in this summary has passed all acceptance criteria established within each protocol.

The following bench tests have been submitted with the 510k:

- Mechanical Resection Performance
- Mechanical Resection Reliability
- Software Automation Verification
- Disconnection Force Testing, RF Wands
- Motor Drive Unit and Foot Pedal Pull Force Verification
- Fluid Control Module Verification
- Storage Environmental Verification
- Environmental Operation Verification
- Foot Pedal Environmental Operation Verification
- Packaging Design Verification for Controller
- Audible Notifications, Reset, and Power Cycling
- Design Verification Physical characteristics
- EMI/EMC Testing (IEC 60601-1-2)
- Electrical Safety Testing (IEC 60601-1, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-2-2, IEC 60601-1-9)

12) Software and Cybersecurity Summary:

The system consists of a controller unit and a wired foot pedal. The INTELLIO SHIFT Controller has a graphical user interface (GUI) which provides user prompts, alarms and indicators, and system diagnostic text.

The INTELLIO SHIFT System Software provides start-up and control of the system, enables the actual input and activation of the system features, and loads MR and RF parameters that allow for MDU motor speed, RF current output, and General Controller settings.

The Controller Software is packaged into a single INTELLIO SHIFT “NEO” Controller Bundle Software package.

The Foot Pedal Software component resides on the foot pedal, and it interacts with RF Main Software to communicate the user actions from foot pedal. RF Main software then relays the foot pedal messages to remaining software components for further process and actions.

The cybersecurity posture of the INTELLIO SHIFT System Software has been comprehensively assessed. The known cybersecurity risks have been identified and the proper mitigations and controls have been identified.

13) Conclusion

The submission demonstrates that (1) any differences in technological characteristics of the predicates do not raise any new questions of safety and efficacy and (2) the proposed device is at least as safe and effective as the predicates. It is concluded that the information included in this summary supports substantial equivalence.