May 2, 2024

CenterPoint Systems LLC
Conner Johnson
Regulatory/Quality Associate
3338 Parkway Blvd
West Valley City, Utah 84119

Re: K233752
Trade/Device Name: Dragonfly™ Pancreaticobiliary Scope; Dragonfly™ Digital Controller; Dragonfly™ Instrument Channel Caps
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FBN, NTN, FET, ODC
Dated: April 2, 2024
Received: April 2, 2024

Dear Conner Johnson:

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology 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)*
K233752

Device Name
Dragonfly™ pancreaticobiliary scope; Dragonfly™ digital controller; Dragonfly™ instrument channel caps

Indications for Use *(Describe)*
The Dragonfly Pancreaticobiliary Scope is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.

The Dragonfly Digital Controller is intended to provide illumination power and receive, process and output images from the Dragonfly Pancreaticobiliary Scope for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.

The Dragonfly Instrument Channel Caps are used to cover the opening to the biopsy/suction channel inlet of an Olympus®, Fujifilm® or Pentax® duodenoscope. The Instrument Channel Caps are intended for exclusive use with the Dragonfly Pancreaticobiliary Scope to provide access for passage, while maintaining insufflation and minimizing leakage of biomaterial from the biopsy port throughout the gastrointestinal endoscopic procedure.

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 OMB number."

510(K) SUMMARY

1 SUBMITTER

Name:	CenterPoint Systems LLC
Address:	3338 Parkway Blvd West Valley City, UT
Phone:	877-848-0828
Contact Person:	Conner Johnson
Date Prepared:	December 21, 2023

2 DEVICE

Name of Device:	Dragonfly Pancreaticobiliary Scope System
Common or Usual Name:	Pancreaticobiliary Scope
Classification Name:	Endoscope and accessories
Regulatory Class:	Class II per 21 CFR 876.1500
Product Code:	FBN, NTN, FET

Name of Device:	Dragonfly Instrument Channel Caps
Common or Usual Name:	Instrument Caps
Classification Name:	Endoscope and accessories
Regulatory Class:	Class II per 21 CFR 876.1500
Product Code:	ODC

3 PREDICATE DEVICES

Predicate Name and 510(k) Number: SpyGlass Visualization System, K181439

This predicate has not been subject to a design-related recall.

No reference predicates were used in this submission.

Predicate Name and 510(k) Number: BioShield biopsy valve EUS – Linear, K202583

This predicate has not been subject to a design-related recall.

No reference predicates were used in this submission.

4 DEVICE DESCRIPTION

Dragonfly Pancreaticobiliary Scope and Digital Controller

The Dragonfly Pancreaticobiliary Scope is a sterile, single-use endoscope used for single-operator per-oral 2holoangiopancreatoscopy. The Dragonfly Pancreaticobiliary System is comprised of two components: The Dragonfly Pancreaticobiliary Scope and the Dragonfly Digital Controller.

The Dragonfly Pancreaticobiliary Scope System is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts. The Dragonfly Pancreaticobiliary Scope is a single-use catheter which provides direct visualization with a camera and illumination, and enables access and delivery of accessories to targeted pancreaticobiliary anatomy. The Dragonfly Pancreaticobiliary Scope comprises of a handle, a catheter, imaging and illumination elements, and a video connection mechanism. The Dragonfly Digital Controller is a reusable accessory which controls illumination and receives, processes, and outputs video signals from the Dragonfly Pancreaticobiliary Scope. The system does not treat or diagnosis conditions.

Dragonfly Instrument Channel Caps

The Dragonfly Instrument Channel Caps, which are included in package with the Dragonfly Pancreaticobiliary Scope, are used to cover the opening to the biopsy/suction channel inlet of a Olympus®, Fujifilm® or Pentax® duodenoscope. The Instrument Channel Caps are intended for exclusive use with the Dragonfly Pancreaticobiliary Scope to provide access for passage, while maintaining insufflation and minimizing leakage of biomaterial from the biopsy port throughout the gastrointestinal endoscopic procedure.

5 INDICATIONS FOR USE

Dragonfly Pancreaticobiliary Scope and Digital Controller

The Dragonfly Pancreaticobiliary Scope is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.

The Dragonfly Digital Controller is intended to provide illumination power and receive, process and output images from the Dragonfly Pancreaticobiliary Scope for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.

Dragonfly Instrument Channel Caps

The Dragonfly Instrument Channel Caps are used to cover the opening to the biopsy/suction channel inlet of a Olympus®, Fujifilm® or Pentax® duodenoscope. The Instrument Channel Caps are intended for exclusive use with the Dragonfly Pancreaticobiliary Scope to provide access for passage, while maintaining insufflation and minimizing leakage of biomaterial from the biopsy port throughout the gastrointestinal endoscopic procedure.

6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE – DRAGONFLY PANCREATICOBILIARY SCOPE AND DIGITAL CONTROLER

The proposed Dragonfly Pancreaticobiliary Scope System and the predicate SpyGlass Visualization System (K181439) are similar in indications for use, intended use, and technological characteristics, and principles of operation.

The differences between the Proposed Device and the Predicate Device are minor and raise no different questions of safety and effectiveness, thus it was concluded that the Proposed Device is substantially equivalent to the Predicate Device. In accordance with 21CFR807.92(a)(6) a summary of how the technological characteristics of the Proposed Device compares to the Predicate Device is provided below.

Table 1: Dragonfly Pancreaticobiliary Scope Comparison to Predicate Device

Feature	Dragonfly Pancreaticobiliary Scope (proposed device)	Primary Predicate: SpyScope DS Access & Delivery Catheter(K181439)	Same/Different between Proposed & Predicate
Intended Use/Indications for Use (Scope)	The Dragonfly Pancreaticobiliary Scope System is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.	The SpyGlass Visualization System is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.	Same
Device Class	II	II	Same
Product Code	FBN, NTN, FET	FBN, NTN, KQM	Same
Regulation number	21 CFR 876.1500	21 CFR 876.1500	Same
Duration of use	Single-use, Transient	Single-use, Transient	Same
Insertion Method	Through a duodenoscope	Through a duodenoscope	Same
Sterilization	Ethylene Oxide	Ethylene Oxide	Same
Prescription Device	Yes	Yes	Same
Working Channel Inner Diameter	5.1F	3.6F	Different (Substantially Equivalent)
Working Length	139cm	214cm	Different (Substantially Equivalent)
Type of image sensor	CMOS	CMOS	Same
Illumination Type	LED	LED	Same
Field of View	120 degrees	120 degrees	Same
Outer Shaft Diameter (Proximal)	3.6mm	3.6mm	Same

Feature	Dragonfly Pancreaticobiliary Scope (proposed device)	Primary Predicate: SpyScope DS Access & Delivery Catheter(K181439)	Same/Different between Proposed & Predicate
Outer Shaft Diameter (Distal)	3.6mm	3.5mm	Different (Substantially Equivalent)
Articulation	Yes, using deflection knobs on handle	Yes, using deflection knobs on handle	Same
Materials/ Biocompatibility	Standard medical device materials, including PEBAX, PTFE, Stainless Steel As described in the 510(k) the materials above were tested during biocompatibility testing. The biocompatibility tests demonstrates that there are no adverse biocompatibility risks associated with use of this material. All test results met the requirements of ISO 10993-1.	Standard medical device materials. The biocompatibility tests demonstrates that there are no adverse biocompatibility risks associated with use of this material. All test results met the requirements of ISO 10993-1.	Same
Features	Handle, Deflection knobs, Umbilical Cable, Accessory Working Channel, Irrigation Ports,	Handle, Articulation Lever, Umbilical Cable, Accessory Access Port, Irrigation Port	Same
Video Processing Unit	Separate VPU which connects to an existing monitor.	Separate VPU which connects to an existing monitor	Same
Direction of View	0 degrees	0 degrees	Same
Minimum Duodenoscope Working Channel	4.2mm	4.2mm	Same
EMC Safety Testing	Complies with applicable clauses of IEC-60601	Complies with applicable clauses of IEC-60601	Same

Table 2: Dragonfly Digital Controller Comparison to Predicate Device

Feature	Dragonfly Digital Controller	Primary Predicate: SpyGlass DS Digital Controller (K181439)	Same/Different between Proposed & Predicate
Intended Use/Indications for Use (Controller)	The Dragonfly Digital Controller **is intended to provide illumination** power **and receive, process and output images from the** Dragonfly Pancreaticobiliary Scope **for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.**	The SpyGlass DS Digital Controller **is intended to provide illumination and receive, process, and output images from the** SpyScope DS Access and Delivery Catheter or SpyScope DS II Access and Delivery Catheter **for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.**	Different (Substantially Equivalent)

Feature	Dragonfly Digital Controller	Primary Predicate: SpyGlass DS Digital Controller (K181439)	Same/Different between Proposed & Predicate
Device Class	II	II	Same
Product Code	FBN	FBN	Same
Regulation number	21 CFR 876.1500	21 CFR 876.1500	Same
Video Outputs	DVI	S-video, VGA or DVI	Same
White Balancing	Automatic	Automatic	Same
Brightness Control	Yes	Yes	Same
Separate Monitor	Yes	Yes	Same
Energy used/Power source	Yes	Yes	Same
Reusability	Yes	Yes	Same
EMC Safety Testing	Complies with applicable clauses of IEC-60601	Complies with applicable clauses of IEC-60601	Same

7 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE – DRAGONFLY INSTRUMENT CHANNEL CAPS

The proposed Dragonfly Instrument Channel Caps and the predicate BioShield biopsy valve EUS – Linear (K202583) are similar in indications for use, intended use, and technological characteristics, and principles of operation.

The differences between the Proposed Device and the Predicate Device are minor and raise no different questions of safety and effectiveness, thus it was concluded that the Proposed Device is substantially equivalent to the Predicate Device. In accordance with 21CFR807.92(a)(6) a summary of how the technological characteristics of the Proposed Device compares to the Predicate Device is provided below.

Feature	**Dragonfly Instrument Caps (proposed device)**	**Primary Predicate: BioShield biopsy valve EUS – Linear (K202583)**	**Same/Different between Proposed & Predicate**
Intended Use	The Dragonfly Instrument Channel Caps are intended to cover the opening to the biopsy/suction channel of flexible echoendoscopes. It provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.	The BioShield biopsy valve EUS – Linear (K202583) is intended to cover the opening to the biopsy/suction channel of flexible echoendoscopes. It provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.	Same
Indications for Use	The Dragonfly Instrument Channel Caps are used to cover the opening to the biopsy/suction channel inlet of a Olympus®, Fujifilm® or Pentax® duodenoscope. The Instrument Channel Caps are intended for exclusive use with the Dragonfly Pancreaticobiliary Scope to provide access for passage, while maintaining insufflation and minimizing leakage of biomaterial from the biopsy port throughout the gastrointestinal endoscopic procedure.	The single use BioShield@ biopsy valve EUS is used to cover the opening to the biopsy/suction channel of flexible echoendoscopes. It provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure and provides access for irrigation.	Different (Substantially Equivalent)
Device Class	II	II	Same

Feature	Dragonfly Instrument Caps (proposed device)	Primary Predicate: BioShield biopsy valve EUS – Linear (K202583)	Same/Different between Proposed & Predicate
Regulation number	21 CFR 876.1500	21 CFR 876.1500	Same
Duration of use	Single-use, Transient	Single-use, Transient	Same
Construction	Cap	Valve Body, Valve Cap	Different (Substantially Equivalent)
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Sterilization Assurance Level	10^{-6}	10^{-6}	Same
Prescription Device	Yes	Yes	Same
Device Dimensions	Length: 0.615” Width: 0.615” Height: 0.480”	Length: 0.52” Width: 0.52” Height: 0.77”	Different (Substantially Equivalent)
Target Population	GI Endoscopic procedures	GI Endoscopic procedures	Same
Energy used/delivered	None	None	Same
Method of application	Manual application	Manual application	Same
Compatible endoscopes	Olympus, Pentax, FujiFlim duodenoscopes	Linear echoendoscopes	Different (Substantially equivalent)
Materials/ Biocompatibility	Silicone	Thermoplastic elastomer	Same

8 PERFORMANCE DATA

All necessary performance testing has been conducted on the Dragonfly Pancreaticobiliary Scope System and Instrument Channel Caps to assure substantial equivalence to the predicate devices and to demonstrate the device performs as intended. All testing was performed on test units representative of finished devices. The device passed the following tests:

- Biocompatibility testing per FDA Final Guidance Document, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (2023)
- Sterilization validation per ANSI/AAMI/ISO 11135
- Packaging validation per ANSI/AAMI/ISO 11607-1
- Electrical Safety and electromagnetic (EMC) Testing per applicable requirements of IEC 60601-1, IEC 60601-1-2, & IEC 60601-2-18.
- Simulated use testing, including use with ancillary devices
- Scope and controller Dimensional verification, including distal OD, working length, working channel length and ID
- Deflection verifications
- Image testing, including illumination verification, Field of View and direction measurement, camera function, camera light ingress and glare
- HDMI compatibility
- Image functionality and gain function
- Sheath compatibility
- Leak test
- Tensile tests
- Optics testing, including Resolution, Depth of Field, Field of View, Geometric distortion, Signal-to-Noise Ratio, Dynamic Range, Image intensity uniformity, color performance

9 CONCLUSION

Upon reviewing the information provided in this submission and comparing the intended use, principle of operation and overall technological characteristics, the is substantially equivalent to existing legally marketed devices.