September 12, 2025

Tangent Endoscopy LLC
℅ Diane Horwitz
Regulatory Consultant
TAG3 Engineering
1161 Sawgrass Corporate Parkway
Sunrise, Florida 33323

Re: K251170
Trade/Device Name: Tangent Single-Use Digital System: Tangent Single-Use Digital Catheter and Tangent Digital Controller
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FBN, NTN, FET
Dated: August 7, 2025
Received: August 8, 2025

Dear Diane Horwitz:

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,

SIVAKAMI VENKATACHALAM -S

for
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

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.	K251170

Please provide the device trade name(s).

Tangent Single-Use Digital System: Tangent Single-Use Digital Catheter and Tangent Digital Controller

Please provide your Indications for Use below.

The Tangent Single-Use Digital System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts. The Tangent Single-Use Digital System comprises two components: the Tangent Single-Use Digital Catheter and the Tangent Digital Controller.

The Tangent Single-Use Digital Catheter is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

The Tangent Digital Controller is intended to provide illumination and receive, process, and output images from the Tangent Single-Use Digital Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.

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)

TANGENT
ENDOSCOPY

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. GENERAL INFORMATION

1.1 Submitter and 510(k) Owner

Tangent Endoscopy LLC
2140 S. Dupont Highway
Camden, DE 19934

1.2 Official Correspondent

Diane Horwitz, Ph.D.
Regulatory, TAG3 Engineering
1161 Sawgrass Corporate Parkway
Sunrise FL 33323
Phone (703) 307-2921
E-mail: dhorwitz@tag3engineering.com

1.3 Date of Preparation

April 11, 2025

2. NAME OF THE DEVICE

2.1 Trade/Proprietary Name

Tangent Single-Use Digital System (Tangent Single-Use Digital Catheter and Tangent Digital Controller)

2.2 Common/Usual Name

Choledochoscope and accessories, flexible/rigid

2.3 Classification

Trade Name	Tangent Single-Use Digital System (Tangent Single-Use Digital Catheter and Tangent Digital Controller)
Common Name	Endoscope and Accessories;
Product codes	FBN, NTN, FET
Device Class and Panel	Class II, Gastroenterology/urology
Classification Regulation	21 CFR 876.1500

3. PREDICATE DEVICE

The predicate device is the SpyGlass Discover Digital System (K200483).

4. DESCRIPTION OF THE DEVICE

The Tangent Single-Use Digital System, consisting of the Tangent Single-Use Digital Catheter and Tangent Digital Controller, is used in diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.

The Tangent Single-Use Digital Catheter is a single-use sterile imaging catheter that enables access and delivery of accessories to targeted portions of the pancreaticobiliary anatomy and displays live video when connected to the Tangent Digital Controller. It includes an articulation control knob, an articulation thumb lever, a locking thumb lever, an irrigation port with Luer fitting, aspiration port with control valve, working channel for accessories and irrigation/ aspiration, LEDs to illuminate the image and wiring to transmit video and image signals to the Tangent Digital Controller. Four-way steerable navigation is provided to the distal tip. The distal tip of the TD Catheter includes the Omnivision image sensor and two LEDs, allowing the sensor to capture clear images or videos of the internal structures. LEDs are located at the distal openings of the two irrigation channels and the large working channel. The Tangent Digital Catheter cable is used to connect the Tangent Digital Catheter handle to the front of the Tangent Digital Controller.

The Tangent Digital Controller is an endoscopic viewing imaging controller that is required for use of the Tangent Single-Use Digital System. The Tangent Digital Controller provides the electronics to control camera function and LEDs at the catheter tip. The Tangent Digital Controller receives video signals from the Tangent Digital Catheter, processes the video signals, and outputs video images to a video monitor. Images and/or videos may be exported. The Tangent Digital Controller provides direct visualization of the pancreaticobiliary duct anatomy and enables exploratory and endotherapy procedures.

5. INTENDED USE

The intended use / indications for use for the Tangent Single-Use Digital System (Tangent Single-Use Digital Catheter and Tangent Digital Controller) is as follows:

> The Tangent Single-Use Digital System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts. The Tangent Single-Use Digital System comprises two components: the Tangent Single-Use Digital Catheter and the Tangent Digital Controller.
>
> The Tangent Single-Use Digital Catheter is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

The Tangent Digital Controller is intended to provide illumination and receive, process, and output images from the Tangent Single-Use Digital Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.

6. SUBSTANTIAL EQUIVALENCE

The proposed Tangent Single-Use Digital System is substantially equivalent in design, features and functionality to the SpyGlass Discover Digital System (K200483). The intended use and indications for use of the subject and predicate are the same aside from the product name.

The technological similarities of the subject device and the predicate are shown in Table 1 below. The differences (smaller shaft OD, larger working channel ID, LEDs vs. optical fibers, and video/ image capture capability)[1] have been demonstrated not to raise new issues of safety or effectiveness.

Table 1. Technology Comparison Between Tangent Single-Use Digital System and Predicate

	Tangent Single-Use Digital System Subject Device	**SpyGlass Discover Digital System K200483 Predicate Device**
Working Length	650 mm	650 mm
Total Length	950 mm	800 mm
Shaft OD	9.9 Fr (3.3 mm)	10.8 Fr (3.6 mm)
Working Channel (Vacuum Channel) ID	4.8 Fr (1.6 mm)	3.6 Fr (1.2 mm)
Compatible Catheter and Controller	Tangent Single-Use Digital Catheter Tangent Digital Controller	SpyGlass Discover Digital Catheter SpyGlass Discover Digital Controller
Compatible medical devices	• Accessory devices with a minimum working length of 81 cm (31.9 in.) and compatible with a 1.6 mm (4.8 F) working channel diameter. • Irrigation sources with a supply line having a male luer-type connector. • Guidewires with a maximum OD of 0.035 in (0.9 mm). • Introducer sheaths or trocars with a minimum diameter of 3.3 mm.	• Accessory devices with a minimum working length of 81 cm (31.9 in.) and compatible with a 1.2 mm (3.6 F) working channel diameter. • Irrigation sources with a supply line having a male luer-type connector. • Guidewires with a maximum OD of 0.035 in (0.9 mm). • Introducer sheaths or trocars with a minimum diameter of 3.6 mm.
Steerable tip	Yes. 4-way deflection	Yes. 4-way deflection
Angulation range	30 degrees with accessory device in working channel.	30 degrees with accessory device in working channel.
Radiopacity	Yes	Yes
Single or multiple use	Single Use	Single Use
Irrigation channels and irrigation port	Yes; 2 dedicated irrigation channels, 1 irrigation port	Yes; 2 dedicated irrigation channels, 1 irrigation port
Aspiration port	Yes; aspiration channel	Yes; aspiration channel
Compatible Display	HD medical grade monitors	Sony LMD1951MD monitor Sony LMD1950MD monitor

[1] Technology differences are identified with blue font in Table 1.

Table 1. Technology Comparison Between Tangent Single-Use Digital System and Predicate

	Tangent Single-Use Digital System Subject Device	SpyGlass Discover Digital System K200483 Predicate Device
Resolution (pixels)	400 x 400	320 x 320
Digital Video Technology	Digital	Digital
Illumination	LEDs at the catheter tip	LEDs in controller that illuminate optical fibers at the catheter tip
Image/Video Capture	Yes	No
Field of View FOV (degrees) (diagonal)	120	120
Direction of View DOV (degrees)	0	0
DOF (mm)	42	40
Optimum Working Distance (mm)	[2, 24]	[2, 24]
SNR (Q)	35.9	29.6
Dynamic Range ((DR) f-stops)	9.5	8.28
Geometric Distortion (GD) (LGD corner)	-11.0	-16.5
IIU (%)	97	88
Color Difference CD (median ΔE)	9.60	12.76
Video Latency (milliseconds)	161	298
Light Output intensity @ z= 4mm (Lux)	15,526	14,900
Compatible Display	HD medical grade monitors	Sony LMD1951MD monitor Sony LMD1950MD monitor
Resolution (pixels)	400 x 400	320 x 320

7. PERFORMANCE TESTING

Bench performance tests, including optical testing, biocompatibility, sterilization and packaging validation, shelf-life validation, cleaning and disinfection validation, electrical safety and electromagnetic compatibility testing, and software verification and validation testing support the substantial equivalence between the Tangent Single-Use Digital System and the predicate device.

8. CONCLUSIONS

This 510(k) submission demonstrates that the Tangent Single-Use Digital System is substantially equivalent to the predicate device.