December 17, 2024

ASAHI Intecc Co., Ltd.
℅ Candace Cederman
Principal Consultant
CardioMed Device Consultants
1783 Forest Drive
Suite 254
Annapolis, Maryland 21401

Re: K241801
Trade/Device Name: Tornus ES
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE
Dated: November 15, 2024
Received: November 18, 2024

Dear Candace Cederman:

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,

Anthony Lee -S

Anthony Lee, Ph.D., M.B.A.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241801

Device Name

Tornus ES

Indications for Use *(Describe)*

This device is used to dilate strictures in the pancreatobiliary systems and to dilate openings via the transgastric or transduodenal wall. This device is indicated for adult use only.

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.

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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 OMB number."

510(k) Summary
[as required by 21 CFR 807.92(c)]

Tornus ES
510(k) K241801

DATE PREPARED:	December 10, 2024
APPLICANT	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho, Seto Aichi 489-0071 Japan
CONTACT	Yoshi Terai President/CEO ASAHI INTECC USA, INC. 3002 Dow Avenue, Suite 212 Tustin, CA 92780 US Tel: (949) 756-8252, FAX: (949) 756-8165 e-mail: ASAHI.ra-fda@ASAHI-intecc.com
TRADE NAME:	Tornus ES
DEVICE CLASSIFICATION:	Class II per 21 CFR §876.5010
CLASSIFICATION NAME:	Biliary catheter and accessories
PRODUCT CODE	FGE
PREDICATE DEVICE:	Soehendra Biliary Dilatation Catheter (K171548)
REFERENCE DEVICE:	Cook Dilator Sets (K183036) Zimmon Pancreatic Stent Sets (K172057) Soehendra Stent Retriever (K161203) Cysto-Gastro Sets (K211909)

INDICATIONS FOR USE:

This device is used to dilate strictures in the pancreatobiliary systems and to dilate openings via the transgastric or transduodenal wall. This device is indicated for adult use only.

DETAILED DESCRIPTION

The Tornus ES is a rotary-operated dilator designed for use in bile duct/pancreatic duct strictures and via transgastric/transduodenal dilation of openings.

The Tornus ES is comprised of stainless-steel coils and polymeric materials. The Dilation and Shaft segments are composed of coils materials that are welded together.

The Tornus ES is available for prescription use only.

DILATION SEGMENT

The coil of the Dilation portion of the device is a dual coil design consisting of an upper layer Wire coil and a Rope coil under layer. The distal side of the dilation segment is tapered, and the surface is coated with Resin and a Hydrophilic coating.

A tapered metal tip is welded to the tip of the coil. This metal tip is available in two applicable guidewire diameters: 0.018 inch and 0.025 inch.

SHAFT

The Shaft coil is also a dual coil design consisting of a rope coil in both the upper and under layers.

The proximal end of the coil is coated with polyurethane, and a grip is bonded to it using an adhesive.

PRINCIPAL OF OPERATION

The Tornus ES is advanced as the physician rotates the grip, in a fashion similar to that of a screw, due to the spiral-wound wire coil design. Once the target site is reached, the site is expanded via the outer diameter of the device's tapered shape.

COMPARISON WITH PREDICATE DEVICES:

The subject device has similar intended use and indication for use as compared with the predicate device. The subject device has similar technological characteristics as the predicate devices. While differences exist between the subject and predicate device, with respect to the access point, those differences do not raise different/new questions of safety and/or effectiveness

Comparison with Predicate Device

Device Name	Subject	Predicate	Reference			
	Tornus ES	**Soehendra Biliary Dilation Catheter**	**Cook Dilator Sets**	**Zimmon Pancreatic Stent Sets**	**Soehendra Stent Retriever**	**Cysto-Gastro Sets**
Manufacturer	ASAHI INTECC	Wilson-Cook Medical	Cook Incorporated	Cook Ireland Ltd.	Wilson-Cook Medical	G-Flex Europe SPRL
510(k)	K241801	K171548	K183036	K172057	K161203	K211909
Classification Panel	Gastroenterology/ Urology	Gastroenterology/ Urology	Cardiovascular/ Gastroenterology/ Urology	Gastroenterology/ Urology	Gastroenterology/ Urology	Gastroenterology/ Urology
Regulation	21 CFR 876.5010	21 CFR 876.5010	21 CFR 870.1310 21 CFR 876.5010	21 CFR 876.5010	21 CFR 876.5010	21 CFR 876.4300
Common Name	Dilatation Catheter	Dilatation Catheter	Dilator, vessel, for percutaneous catheterization / stents, drains and dilators for the biliary ducts	Drainage Catheter	Stent Retriever	Endoscopic electrosurgery device
Product Code	FGE	FGE	DRE, FGE	FGE	FGE	KNS
Class	Class II	Class II	Class II	Class II	Class II	Class II
Indication for Use	This device is used to dilate strictures in the pancreatobiliary systems and to dilate openings via the transgastric or transduodenal wall. This device is indicated for adult use only.	Soehendra Biliary Dilatation Catheters are used to dilate biliary strictures. These devices are indicated for adult use only	Intended to be used for dilating puncture sites or catheter tracts for percutaneous placement of devices for vascular and non-vascular applications such as in the venous, arterial, biliary and renal systems.	Zimmon Pancreatic Stent sets are used to drain obstructed pancreatic ducts	Used to remove stents from the biliary and pancreatic duct(s) while maintaining wire guide placement	Cysto-Gastro Sets are intended to be used to electrosurgically cannulate pancreatic pseudo-cysts endoscopically (via the transgastric or transduodenal wall) as an alternative to surgical or percutaneous treatment.

Device Name	Subject	Predicate	Reference			
	Tornus ES	**Soehendra Biliary Dilation Catheter**	**Cook Dilator Sets**	**Zimmon Pancreatic Stent Sets**	**Soehendra Stent Retriever**	**Cysto-Gastro Sets**
Design Feature/Main Components	Rope coil Resin coating Hydrophilic coating Metal tip Grip	Catheter shaft Marker ring Luer lock hub	Dilator shaft, coating (hydrophilic), guidewire port	Stent Introducer	Handle Rope coil Tapered threaded screw type distal tip	Metal Tip Needle (Depends on lineup) Catheter Handle with electrode
Material	Stainless Steel, Polyurethane elastomer, Acrylic resin, PVP, Nitrocellulose, Polypropylene	Unknown	Resin Hydrophilic coating	Polyethylene EVA	Stainless Steel Resin	Stainless Steel, Teflon, POM + MABS
O.D. (Dilation)^	7 Fr (2.62 mm)	6 – 10 Fr (2.0 – 3.3 mm)	3.0 – 26.0 Fr (1.0 – 8.7 mm)	3 – 11.5 Fr (1.66 – 2.66 mm)	8 Fr (2.70 mm)	6, 8.5 and 10 Fr (2.0 – 3.3 mm)
Effective Length	195 cm	200 cm	6 – 65 cm	Stent length: 2 – 15 cm Introducer length: 170cm	168 cm	180 and 210 cm
Guidewire Diameter (in)	0.018” 0.025”	0.035”	Unknown	0.035”	0.018” 0.035”	0.035”
Sterilization	EO	Unknown	EO	EO	EO	EO
Shelf Life	3 years	Unknown	3 years	3 years	3 years	3years

^ The shaft O.D of the Tornus ES is 2.64mm, with a Tip ID of either 0.018” or 0.025”

NON CLINICAL TESTING / PERFORMANCE DATA:

Non clinical laboratory testing was performed on the Tornus ES to determine substantial equivalence. The following testing/assessments were performed:

Test item	Test Results
Appearance	Pass
Tensile strength	Pass
Guidewire pass-through ability	Pass
Dilation ability	Pass
Slide durability	Pass
Radio-detectability	Pass
Corrosion resistance	Pass
Polyurethane strength	Pass
Guide wire trackability	Pass
Kink resistance	Pass
Dimension measurement	Pass
Simulated use and (torsional strength)	Pass

The *in vitro* bench tests demonstrated that the Tornus ES met all acceptance criteria. Performance data demonstrate that the device functions as intended and is substantially equivalent to the predicate and reference devices.

BIOCOMPATIBILITY:

The Tornus ES was tested in accordance with ISO 10993 and found to be biocompatible. The following tests were performed:

Test Method	Standard	Acceptance Criteria	Results
Cytotoxicity MEM Elution Test	ISO 10993-5 No deviations	The test system is considered suitable if no signs of cellular reactivity (Grade 0) are noted for both the negative control article and the medium control.	Non-cytotoxic
Sensitization KLIGMAN Maximization Test	ISO 10993-10 No deviations	The extracts should show no evidence of causing delayed dermal contact sensitization in the guinea pig.	Non-Sensitizing
Irritation Intracutaneous Injection Test	ISO 10993-10 No deviations	The test extract and the negative control must exhibit similar edema and erythema scores.	Non-Irritant
Systemic Toxicity Acute System Toxicity Test	ISO 10993-11 No deviations	The test article must not show significantly greater biological activity than the control.	Non-toxic
Systemic Toxicity Rabbit Pyrogen Test (material mediated)	ISO 10993-11 No deviations	The test article should not increase the rectal temperature of any of the animals by more than 0.5 degrees Celsius.	Non-pyrogenic

STERILIZATION AND SHELF LIFE:

The Tornus ES sterilization process using Ethylene Oxide (EO) has been validated in accordance with ISO 11135: 2014 to achieve a sterility assurance level (SAL) of 10^{-6}. EO and Ethylene Chlorohydrin (ECH) residuals were below the limits specified in ISO 10993-7:2008.

Both baseline and accelerated shelf-life testing were conducted demonstrating the device will perform as intended to support the proposed 3-year shelf-life.

CONCLUSION:

The Tornus ES have the similar intended use and indications, and the same or similar technological characteristics such as design, materials, sterilization method, performance, and operating principles as the predicate and reference device. Performance data demonstrates that the device functions as intended.