March 17, 2026

C.R. Bard, Inc.
Matthew Rather
Senior Regulatory Affairs Specialist
8195 Industrial Blvd.
Covington, Georgia 30014

Re: K252971
Trade/Device Name: Elyra™ Thulium Fiber Laser System and Elyra™ Plus Thulium Fiber Laser System (Laser, Fibers, and Accessories)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 17, 2025
Received: September 17, 2025

Dear Matthew Rather:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2026.03.17 20:15:50 -04'00'

for Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252971

Device Name
Elyra™ Thulium Fiber Laser System and Elyra™ Plus Thulium Fiber Laser System (Laser, Fibers, and Accessories)

Indications for Use *(Describe)*

Elyra™ Thulium Fiber Laser System
The Elyra™ TFL System (Laser, Fibers, and Accessories) is intended for incision, excision, resection, ablation, coagulation and hemostasis of soft tissue, with or without an endoscope, in the following indications: urology and lithotripsy.

Urology
• Condylomas
• Urethral strictures
• Lesions of external genitalia
• Bladder neck incisions (BNI)
• Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors
• Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi
• Treatment of distal impacted fragments remaining in the ureters following lithotripsy

Lithotripsy and Percutaneous Urinary Lithotripsy
• Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate monohydrate, and calcium oxalate dihydrate stones
• Endoscopic fragmentation of calculi
• Treatment of distal impacted fragments of steinstrasse when guidewire cannot be passed

Elyra™ Plus Thulium Fiber Laser System
The Elyra™ Plus TFL System (Laser, Fibers, and Accessories) is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in the following indications: urology and lithotripsy.

Urology
• Ablation of Benign Prostatic Hyperplasia (Hypertrophy) [BPH]
• Laser Resection of the Prostrate (LRP)
• Laser Enucleation of the Prostate (LEP)
• Laser Ablation of the Prostate (LAP)
• Transurethral Incision of the Prostate (TUIP)
• Condylomas
• Urethral strictures
• Lesions of external genitalia
• Bladder neck incisions (BNI)
• Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors
• Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi
• Treatment of distal impacted fragments remaining in the ureters following lithotripsy

Lithotripsy and Percutaneous Urinary Lithotripsy Indications
• Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate monohydrate, and calcium oxalate dihydrate stones

• Endoscopic fragmentation of calculi
• Treatment of distal impacted fragments of steinstrasse when guidewire cannot be passed

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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510(k) Summary – K252971

Elyra™ and Elyra™ Plus Thulium Fiber Laser System

510(k) Owner: C. R. Bard Inc.
8195 Industrial Boulevard
Covington, GA 30014 USA
+1.844.823.5433

Contact Person: Matthew Rather
Senior Regulatory Affairs Specialist
E-mail: matthew.rather@bd.com

Date Prepared: March 11, 2026

Subject Device Name: **Elyra™ Thulium Fiber Laser System and Elyra™ Plus Thulium Fiber Laser System (Laser, Fibers, and Accessories)**

Subject Device

Device Trade Names:	Elyra™ Thulium Fiber Laser System and Elyra™ Plus Thulium Fiber Laser System (Laser, Fibers, and Accessories)
Common Name:	Powered Laser Surgical Instrument
Regulation Name:	General and Plastic Surgery Devices
Regulation Number:	21 CFR 878.4810
Product Code:	GEX
Regulatory Class:	II
Classification Panel:	General & Plastic Surgery
Prior Correspondence:	Q231350

510(k) Premarket Submission Number: K252971

Predicate Device

510(k) Number:	K183647
Device Trade Name:	SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™Laser Fibers, and Accessories)
Common Name:	Powered Laser Surgical Instrument
Regulation Name:	General and Plastic Surgery Devices
Product Code:	GEX
Regulatory Class:	II
Regulation Number:	21 CFR 878.4810
Classification Panel:	General & Plastic Surgery

Device Description

The Elyra™ Thulium Fiber Laser (TFL) System (Elyra™ Plus, Elyra™, Elyra™ Thulium Laser Fibers and Accessories) is a thulium fiber laser which delivers a pulsed beam of near-infrared light (1940nm) through the active media of a single use or reusable delivery fiber. The system is contained in a mobile format and has an articulating graphical user interface display and built-in laser generator with the ability to connect to standard mains power.

The Elyra™ TFL System is available in two models: the Elyra™ TFL System and the Elyra™ Plus TFL System. The lasers are similar devices with only the following differences:

- maximum average power output
- frequency
- pulse duration
- pulse energy
- maximum peak power
- foot pedal options to activate energy delivery
- vaporization and BPH indications.

The Elyra™ TFL System and Elyra™ Plus TFL System includes a medical laser generator (which includes a blast shield, remote interlock connector, keys, and power cord), delivery fibers, and a footswitch (hybrid or wired). Safety goggles are provided with each system.

The delivery fibers are available in standard tip and ball tip options as single use devices. Reusable fibers are only available in the standard tip option. Each fiber contains a unique radio frequency identification (RFID) tag that will allow the laser generator to identify certain aspects of the fiber, including UDI, catalog number, lot number, manufacture date, expiration date, size, max power and energy, and number of remaining uses (if applicable information once attached). Fibers are only compatible with Elyra™ systems.

Indications for Use

Elyra™ Thulium Fiber Laser System

The Elyra™ TFL System (Laser, Fibers, and Accessories) is intended for incision, excision, resection, ablation, coagulation and hemostasis of soft tissue, with or without an endoscope, in the following indications: urology and lithotripsy.

Urology

- Condylomas
- Urethral strictures
- Lesions of external genitalia
- Bladder neck incisions (BNI)
- Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors
- Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi
- Treatment of distal impacted fragments remaining in the ureters following lithotripsy

Lithotripsy and Percutaneous Urinary Lithotripsy

- Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate monohydrate, and calcium oxalate dihydrate stones
- Endoscopic fragmentation of calculi

- Treatment of distal impacted fragments of steinstrasse when guidewire cannot be passed

Elyra™ Plus Thulium Fiber Laser System

The Elyra™ Plus TFL System (Laser, Fibers, and Accessories) is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in the following indications: urology and lithotripsy.

Urology

- Ablation of Benign Prostatic Hyperplasia (Hypertrophy) [BPH]
- Laser Resection of the Prostrate (LRP)
- Laser Enucleation of the Prostate (LEP)
- Laser Ablation of the Prostate (LAP)
- Transurethral Incision of the Prostate (TUIP)
- Condylomas
- Urethral strictures
- Lesions of external genitalia
- Bladder neck incisions (BNI)
- Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors
- Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi
- Treatment of distal impacted fragments remaining in the ureters following lithotripsy

Lithotripsy and Percutaneous Urinary Lithotripsy Indications

- Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate monohydrate, and calcium oxalate dihydrate stones
- Endoscopic fragmentation of calculi
- Treatment of distal impacted fragments of steinstrasse when guidewire cannot be passed

Substantial Equivalence

Minor differences between the subject and predicate devices were reviewed through performance testing and were determined not to alter the safety and effectiveness when compared to the predicate laser system.

Parameter	**Subject Device:** **Elyra™ Thulium Laser Fiber System** (Elyra™, Elyra™ Plus, Elyra™ Thulium Laser Fibers and Accessories)	**Predicate Device:** **SOLTIVE™ Laser System (K183647)** (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™ Laser Fibers, and Accessories)	Summary
Device Classification Name	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument	Same
FDA Product Code	GEX	GEX	Same
Regulation Number	878.4810	878.4810	Same

Parameter	**Subject Device:** **Elyra™ Thulium Laser Fiber System** (Elyra™, Elyra™ Plus, Elyra™ Thulium Laser Fibers and Accessories)	**Predicate Device:** **SOLTIVE™ Laser System (K183647)** (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™ Laser Fibers, and Accessories)	**Summary**
Indications for Use	The Elyra™ Thulium Fiber Laser System (Laser, Fibers, and Accessories) is intended to be used for incision, excision, resection, ablation, coagulation and hemostasis of soft tissue, with or without an endoscope, in the following indications: urology and lithotripsy. <u>Urology</u> • Ablation of Benign Prostatic Hyperplasia (Hypertrophy) [BPH]* • Laser Resection of the Prostrate (LRP) * • Laser Enucleation of the Prostate (LEP) * • Laser Ablation of the Prostate (LAP)* • Transurethral Incision of the Prostate (TUIP) * • Condylomas • Urethral strictures • Lesions of external genitalia • Bladder neck incisions (BNI) • Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors • Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi • Treatment of distal impacted fragments remaining in the ureters following lithotripsy *Elyra™ Plus Only <u>Lithotripsy and Percutaneous Urinary Lithotripsy Indications</u> • Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate monohydrate, and calcium oxalate dihydrate stones • Endoscopic fragmentation of calculi • Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed	The SOLTIVE™ Laser System (Laser, Fibers, and Accessories) is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery. <u>Urology</u> • Ablation of Benign Prostatic Hyperplasia (Hypertrophy) [BPH] • Laser Resection of the Prostrate (LRP) • Laser Enucleation of the Prostate (LEP) • Laser Ablation of the Prostate (LAP) • Transurethral Incision of the Prostate (TUIP) • Condylomas • Urethral strictures • Lesions of external genitalia • Bladder neck incisions (BNI) • Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors • Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi • Treatment of distal impacted fragments remaining in the ureters following lithotripsy <u>Lithotripsy and Percutaneous Urinary Lithotripsy Indications</u> • Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate monohydrate, and calcium oxalate dehydrate stones • Endoscopic fragmentation of calculi • Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed	Subset

Parameter	Subject Device: **Elyra™ Thulium Laser Fiber System** (Elyra™, Elyra™ Plus, Elyra™ Thulium Laser Fibers and Accessories)	Predicate Device: **SOLTIVE™ Laser System (K183647)** (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™ Laser Fibers, and Accessories)	Summary
		<u>Gastroenterology</u> • Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: ○ Appendectomy ○ Angiodysplasia ○ Polyps ○ Colorectal cancer ○ Biopsy ○ Telangiectasias ○ Gall Bladder calculi ○ Telangiectasias of the Osler-Weber-Renu disease ○ Biliary/Bile duct calculi ○ Vascular Malformation ○ Ulcers ○ Gastritis ○ Gastric ulcers ○ Esophagitis ○ Duodenal ulcers ○ Esophageal ulcers ○ Non-Bleeding Ulcers ○ Varices ○ Pancreatitis ○ Colitis ○ Hemorrhoids ○ Mallory-Weiss tear ○ Cholecystectomy ○ Gastric Erosions ○ Benign and Malignant Neoplasm <u>Gynecology</u> Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue.	
Principle of Operation	Thulium Laser generator with fiber optic delivery	Thulium Laser generator with fiber optic delivery	Same
Sterilization	Ethylene Oxide (Laser Fibers)	Ethylene Oxide (Laser Fibers)	Same
Single Use & Reusable	Single Use: Laser Fibers Reusable: Laser Fibers and Laser Generator Console	Single Use: Laser Fibers Reusable: Laser Fibers and Laser Generator Console	Same

Parameter	Subject Device: **Elyra™ Thulium Laser Fiber System** (Elyra™, Elyra™ Plus, Elyra™ Thulium Laser Fibers and Accessories)	Predicate Device: **SOLTIVE™ Laser System (K183647)** (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™ Laser Fibers, and Accessories)	Summary
Laser Fibers Nominal Core Diameters	**SINGLE USE** **Flat Tip:** 150, 200, 272, 365, 550, 940 µm **Ball Tip:** 150, 200, 272 µm **REUSABLE** **Flat Tip:** 272, 365, 550, 940 µm	**SINGLE USE** **Flat Tip:** 150, 200, 365, 550, 940 µm **Ball Tip:** 150, 200 µm **REUSABLE** **Flat Tip**: 150, 200, 365, 550, 940 µm	Similar
Frequency	1 – 2220 Hz	1 – 2400 Hz	Similar
Wavelength	1920 -1960 nm	1920 -1960 nm	Same
Emission Mode	Pulsed Wave (PW)	Pulsed Wave (PW)	Same
Pulse Duration	50 µs – 60 ms	200 µs – 50 ms	Similar
Pulse Energy	25 – 6000 mJ	25 – 6000 mJ	Same
Average Power	60 W	60 W	Same
Peak Power	500 W	500 W	Same
Operating Conditions	10°C - 30°C 20 -75% (non-condensing)	10°C - 30°C 20%-75% (non-condensing)	Same
Aiming Beam	**Color:** Green **Wavelength:** 500 nm – 550 nm **Power:** 0 mW - 5 mW **Color:** Blue **Wavelength:** 440 nm - 460nm **Power:** 0 mW – 5 mW	**Color:** Green **Wavelength:** 500 nm – 550 nm **Power:** 0 mW - 5 mW	Similar
Electrical Requirement	100-240V~, 50/60 Hz	100-240V~, 50/60 Hz	Same

Biocompatibility Data

Biocompatibility was evaluated to the following standards:

- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices – Part 10: Tests for skin sensitization
- ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices – Part 23: Tests for irritation

Performance Data

Software validation was performed according to the FDA Guidance: *Content of Premarket Submissions for Device Software Functions*. Software documentation was provided in accordance with an enhanced documentation level.

Electromagnetic compatibility and safety was evaluated to the following standards:

- IEC 60601-1:2005/AMD1:2012,AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014/AMD1:2020 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standards: Electromagnetic disturbances – Requirements and tests
- IEC 60601-1-6:2010/AMD1:2013, AMD2:2020 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-2-22:2019 Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825-1:2014 Safety of laser products – Part 1: Equipment classification and requirements

Performance testing of the Elyra™ TFL System was completed to verify all system and software requirements, the result of which confirmed the safe and effective function of the device. No clinical testing was required to evaluate substantial equivalence. Below is a list of the relevant nonclinical tests performed on the Elyra™ TFL System.

- Physical and mechanical verification
- System reliability
- Software verification
- Laser control accuracy
- Electromagnetic compatibility
- Electrical and thermal safety
- Cybersecurity
- Packaging integrity
- Human factors validation

The results from this testing demonstrate that the characteristics and performance criteria of the subject device are substantially equivalent to the predicate device and that the subject device performs in a manner equivalent to devices currently on the market for the same intended use.

Conclusions

The Elyra™ Thulium Fiber Laser System and Elyra™ Plus Thulium Fiber Laser System (Laser, Fibers, and Accessories) are substantially equivalent and do not raise new questions regarding safety and effectiveness when compared to the predicate device.