



October 27, 2025

Patriot Laser, LLC
Frank Ford
Official Applicant
13423 Blanco Road #162
San Antonio, Texas 78216

Re: K251824

Trade/Device Name: Patriot Duo

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: June 3, 2025

Received: June 13, 2025

Dear Frank Ford:

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,

TANISHA
L. HITHE -S

Digitally signed by
TANISHA L. HITHE -S
Date: 2025.10.27
18:05:38 -04'00'

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

Indications for Use

510(k) Number (if known)

K251824

Device Name

Patriot Duo Laser System

Indications for Use (Describe)

The Patriot Duo in the CW mode is intended for Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, Coagulation and hemostasis) of soft tissues including:

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, Coagulation and hemostasis) including: Urethral Strictures, Bladder Neck Incisions (BNI), Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors, Ablation of Benign Prostatic Hypertrophy (BHP), Transurethral incision of the prostate (TUIP), Laser Resection of the Prostate (HoLRP), Laser Enucleation of the Prostate (HoLEP), Laser Ablation of the Prostate (HoLAP), Condylomas and Lesions of external genitalia.

Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: Appendectomy, Polyps, Biopsy, Gall Bladder calculi, Biliary/Bile duct calculi, Ulcers, Gastric ulcers, Duodenal ulcers, Non Bleeding Ulcers, Pancreatitis, Hemorrhoids, Cholecystectomy, Benign and Malignant Neoplasm, Angiodysplasia, Colorectal cancer, Telangiectasias, Telangiectasias of the Osler-Weber-Renu disease, Vascular Malformation, Gastritis, Esophagitis, Esophageal ulcers, Varices, Colitis, Mallory-Weiss tear, Gastric Erosions

Thoracic and Pulmonary

Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue including: Laryngeal Lesions, Airway obstructions including carcinoma, Polyps and Granulomas, Palliation of obstructing carcinomas of the tracheobronchial tree

Gynecology

Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis), Intra-uterine treatment of submucous fibroids, benign endometrial polyps, and uterine septum by incision, excision, ablation and or vessel coagulation, Soft tissue excision procedures such as excisional conization of the cervix

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue) including: Endonasal/sinus Surgery, Partial turbinectomy, Polypectomy, Dacryocystorhinostomy, Frontal Sinusotomy, Ethmoidectomy, Maxillary antrostomy, Functional endoscopic sinus surgery, Lesions or tumors of the oral, nasal, glossal, pharyngeal and, laryngeal, Tonsillectomy, Adenoidectomy

Dermatology and Plastic Surgery

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, dermatologic and aesthetic surgical procedures including: Basal Cell Carcinomas, Lesions of skin and subcutaneous tissue, Skin tags, Plantar warts

General Surgery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization,

coagulation and hemostasis) including: Cholecystectomy, Lysis of adhesion, Appendectomy
Biopsy, Skin incision, Tissue dissection, Excision of external tumors and lesions, Complete or partial
resection of internal organs, tumors and lesions, Mastectomy, Hepatectomy Pancreatectomy,
Splenectomy, Thyroidectomy, Parathyroidectomy, Herniorrhaphy, Tonsillectomy, Lymphadenectomy,
Partial Nephrectomy, Pilonidal Cystectomy, Resection of lipoma, Debridement of Decubitus Ulcer,
Hemorrhoids, Debridement of Stasis Ulcer, Biopsy

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue),
Ablation of soft and cartilaginous tissue in Minimal Invasive Spinal Surgery including: Percutaneous Laser
Disc Decompression/Discectomy, Foraminoplasty, Ablation and coagulation of soft vascular and non
vascular tissue, In minimally invasive spinal surgery

The Patriot Duo in the Quasi-CW (SuperPulse) mode is intended for:

Urology

Ablation of Benign Prostatic 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 dehydrate stones.

Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization,
coagulation and haemostasis) including:
Appendectomy, Polyps, Biopsy, Gall Bladder calculi, Biliary/Bile duct calculi, Ulcers, Gastric ulcers,
Duodenal ulcers, Non Bleeding Ulcers, Pancreatitis, Haemorrhoids, Cholecystectomy, Benign and
Malignant Neoplasm, Angiodysplasia, Colorectal cancer, Telangiectasias, Telangiectasias of the OslerWeber-Renu
disease, Vascular Malformation, Gastritis, Esophagitis, Esophageal ulcers, Varices, Colitis,
Mallory-Weiss tear, Gastric Erosions

Gynecology

Open and laparoscopic gynecological surgery (incision, resection, ablation, vaporization, coagulation and
hemostasis) of the soft tissue.

Note: The Patriot Duo for CW mode is only cleared for BPH when using over 150 W

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) number	K251824
Device Name	Patriot Duo Laser System
510(k) Type	Traditional
Applicant	Patriot Laser, LLC 23030 N 15th Street Phoenix, AZ 85207 October 22 nd , 2025
Applicant Contact	Name: Frank Ford Phone: 210-885-7679 Email: fford1@satx.rr.com
Medical Specialty	General and Plastic Surgery
Regulation	§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.
Product Code	GEX (Class 2) – Powered Laser Surgical Instrument
Predicate Devices	K162334, Patriot 1 K183647, SOLTIVE™ Premium

Device Description

Patriot Laser is seeking to introduce the Patriot Duo Laser, fibers and related accessories into commerce using fibers provided by InnovaQuartz, LLC, previously cleared by the FDA via the Premarket 510(k) notification process K180140, the InnovaQuartz LLC side fire fiber was previously cleared by the Premarket 510(k) notification process K233157.

The Patriot Duo Laser, fibers and related accessories are substantially equivalent to the predicate devices, The U.S. Laser Worx Patriot 1 Family of Lasers, fibers and associated accessories (K162334) and the Olympus Surgical Technologies America Soltive Preimum SuperPulse Laser, Laser fibers and accessories (K183647). The Patriot Duo is essentially the exact same device in the CW mode of operation as the as the Patriot 1 Family of Lasers. The Patriot Duo also employs a Quasi CW (SuperPulse) module allowing the Patriot Duo to operate in both the CW and Quasi CW (SuperPulse) modes to expand the Indications for Use (IFU's) to include Laser Lithotripsy and a variety of other clinical indications in the Quasi CW (SuperPulse) mode.

In the Patriot Duo each mode of operation is completely independent and may not be used at the same time or simultaneously, hence Patriot Laser LLC is simply requesting FDA Premarket Approval of two previously cleared modalities to be available in one system.

The U.S. Laser Worx Patriot 1 Family of lasers and accessories received FDA Premarket clearance April 27, 2017 (K162334) and the Olympus Surgical Technologies America Soltive Preimum SuperPulse Laser, Laser fibers and accessories received FDA Premarket clearance August 10, 2019 (K183647) for its Quasi CW (SuperPulse) Thulium Fiber Laser. Patriot Laser is simply combining two previously cleared technologies into the same console making it more beneficial for the medical community to treat more patients and a wider array of medical conditions using the same device.

The Patriot 1 Family of Lasers, 200, 400, 600 and 1000 micron sterile, disposable, single-use fibers (K162334) are indicated for incision, excision, resection, ablation, vaporization and coagulation of soft tissue encountered urology, gastroenterology, thoracic and pulmonary, gynecology, ENT, dermatology and plastic surgery general surgery and arthroscopy.

The Olympus Surgical Technologies America Soltive Preimum SuperPulse Laser (K183647) 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.

The Patriot Duo Laser, fibers, and related accessories are indicated for incision, excision, resection, ablation, vaporization, and coagulation of soft tissue encountered in urology, lithotripsy, gastroenterology, thoracic and pulmonary, gynecology, ENT, dermatology and plastic surgery general surgery and arthroscopy.

The Patriot Duo, the Patriot 1 Family of Lasers and the Soltive Premium are medical grade, infrared devices, which provide continuous and or Quasi CW (SuperPulse) laser energy at a wavelength 1945.5 nm +/- 8 % and 1920 nm – 1960 nm respectfully. The very slight difference in wavelength is clinically negligible. The Patriot Duo has the same intended uses as the previously cleared devices by the FDA via the 510K Notification process.

A comparison matrix listing the Characteristics and Technical Data of the Patriot Laser Patriot Duo and representative predicate devices is listed below.

The intended use and indications for use of the Patriot Duo Laser, fibers and related accessories are equivalent to the intended use and indications for use of the predicate devices the Patriot 1 Family of Lasers, fibers and related accessories and The Soltive Premium Laser, Laser fibers and accessories.

In addition, similar technological characteristics and principles of operation apply for all three laser systems. The Patriot Duo Laser, fibers and related accessories, components share the same fundamental technology as the previously cleared or predicate devices.

Performance testing was conducted and demonstrated that technological differences in optical and energy outputs of the laser do not alter the safety and effectiveness when compared to the optical and energy outputs of the predicate laser systems.

In regard to safety or effectiveness whereas the Patriot Duo, the Patriot 1 Family of Lasers and the Soltive Premium are very similar products. Patriot Laser believes that the performance characteristics of the Patriot Duo raises no safety concerns.

Summary of Non-Clinical Testing

- Risk analysis activities, in compliance with the requirements of ISO 14971 Third Edition 2019-12. Medical devices - Application of risk management to medical devices
- IEC 60825-1:2014, Safety of laser products – Part 1: Equipment classification and requirements.
- IEC 60601-1:2005, Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance; IEC 60601-1:2005/AMD1:2012/AMD2:2020
- IEC 60601-1-2:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- Software verification and validations, with Basic Documentation, in compliance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 2005 and Content of Premarket Submissions for Device Software Functions, June 2023.

The tests confirmed that the subject device operates in alignment with its specifications and complies with international consensus standards and FDA guidance.

Indications for Use

CW Mode:

The Patriot Duo in the CW mode is intended for Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, Coagulation and hemostasis) of soft tissues including:

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, Coagulation and hemostasis) including: Urethral Strictures, Bladder Neck Incisions (BNI), Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors, Ablation of Benign Prostatic Hypertrophy (BHP), Transurethral incision of the prostate (TUIP), Laser Resection of the Prostate (HoLRP), Laser Enucleation of the Prostate (HoLEP), Laser Ablation of the Prostate (HoLAP), Condylomas and Lesions of external genitalia

Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: Appendectomy, Polyps, Biopsy, Gall Bladder calculi, Biliary/Bile duct calculi, Ulcers, Gastric ulcers, Duodenal ulcers, Non Bleeding Ulcers, Pancreatitis, Hemorrhoids, Cholecystectomy, Benign and Malignant Neoplasm, Angiodysplasia, Colorectal cancer, Telangiectasias, Telangiectasias of the Osler-Weber-Renu disease, Vascular Malformation, Gastritis, Esophagitis, Esophageal ulcers, Varices, Colitis, Mallory-Weiss tear, Gastric Erosions

Thoracic and Pulmonary

Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue including: Laryngeal Lesions, Airway obstructions including carcinoma, Polyps and Granulomas, Palliation of obstructing carcinomas of the tracheobronchial tree

Gynecology

Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis), Intra-uterine treatment of submucous fibroids, benign endometrial polyps, and uterine septum by incision, excision, ablation and or vessel coagulation, Soft tissue excision procedures such as excisional conization of the cervix

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue) including: Endonasal/sinus Surgery, Partial turbinectomy, Polypectomy, Dacryocystorhinostomy, Frontal Sinusotomy, Ethmoidectomy, Maxillary antrostomy, Functional endoscopic sinus surgery, Lesions or tumors of the oral, nasal, glossal, pharyngeal and, laryngeal, Tonsillectomy, Adenoidectomy

Dermatology and Plastic Surgery

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, dermatologic and aesthetic surgical procedures including: Basal Cell Carcinomas, Lesions of skin and subcutaneous tissue, Skin tags, Plantar warts

General Surgery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: Cholecystectomy, Lysis of adhesion, Appendectomy
Biopsy, Skin incision, Tissue dissection, Excision of external tumors and lesions, Complete or partial resection of internal organs, tumors and lesions, Mastectomy, Hepatectomy Pancreatectomy, Splenectomy, Thyroidectomy, Parathyroidectomy, Herniorrhaphy, Tonsillectomy, Lymphadenectomy, Partial Nephrectomy, Pilonidal Cystectomy, Resection of lipoma, Debridement of Decubitus Ulcer, Hemorrhoids, Debridement of Stasis Ulcer, Biopsy

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue), Ablation of soft and cartilaginous tissue in Minimal Invasive Spinal Surgery including: Percutaneous Laser Disc Decompression/Discectomy, Foraminoplasty, Ablation and coagulation of soft vascular and non vascular tissue, In minimally invasive spinal surgery

Quasi-CW (SuperPulse) Mode:**Urology**

Ablation of Benign Prostatic 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 dehydrate stones.

Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including:

Appendectomy, Polyps, Biopsy, Gall Bladder calculi, Biliary/Bile duct calculi, Ulcers, Gastric ulcers, Duodenal ulcers, Non Bleeding Ulcers, Pancreatitis, Haemorrhoids, Cholecystectomy, Benign and Malignant Neoplasm, Angiodysplasia, Colorectal cancer, Telangiectasias, Telangiectasias of the Osler-Weber-Renu disease, Vascular Malformation, Gastritis, Esophagitis, Esophageal ulcers, Varices, Colitis, Mallory-Weiss tear, Gastric Erosions

Gynecology

Open and laparoscopic gynecological surgery (incision, resection, ablation, vaporization, coagulation and hemostasis) of the soft tissue.

Note: The Patriot Duo for CW mode is only cleared for BPH when using over 150 W

Technological Comparison

Comparison with predicate - CW Mode

Specifications	Patriot Duo (K251824)	Patriot 1 (K162334)	Comparison
Indications for Use	<p>The Patriot Duo in the CW mode is intended for Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, Coagulation and hemostasis) of soft tissues including:</p> <p>Urology</p> <p>Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, Coagulation and hemostasis) including: Urethral Strictures, Bladder Neck Incisions (BNI), Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors, Ablation of Benign Prostatic Hypertrophy (BHP), Transurethral incision of the prostate (TUIP), Laser Resection of the Prostrate (HoLRP), Laser Enucleation of the Prostate (HoLEP), Laser Ablation of the Prostate (HoLAP), Condylomas and Lesions of external genitalia</p> <p>Gastroenterology</p> <p>Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: Appendectomy, Polyps, Biopsy</p>	<p>The Patriot 1 Family of Lasers, 400, 600 and 1000 micron sterile, disposable, single use fibers are indicated for incision, excision, resection, ablation, vaporization and coagulation of soft tissue including:</p> <p>Urology</p> <p>Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, Coagulation and hemostasis) including: Urethral Strictures, Bladder Neck Incisions (BNI), Ablation and resection of Bladder Tumors, Urethral Tumors. Ablation of Benign Prostatic Hypertrophy (BHP), Transurethral incision of the prostate (TUIP), Laser Resection of the Prostrate (HoLRP), Laser Enucleation of the Prostate (HoLEP), Laser Ablation of the Prostate (HoLAP), Condylomas Lesions of external genitalia.</p> <p>Gastroenterology</p> <p>Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:</p>	Same

Specifications	Patriot Duo (K251824)	Patriot 1 (K162334)	Comparison
	<p>Gall Bladder calculi, Biliary/Bile duct calculi, Ulcers, Gastric ulcers, Duodenal ulcers, Non Bleeding Ulcers, Pancreatitis, Hemorrhoids, Cholecystectomy, Benign and Malignant Neoplasm, Angiodysplasia, Colorectal cancer, Telangiectasias, Telangiectasias of the Osler-Weber-Renu disease, Vascular Malformation, Gastritis, Esophagitis, Esophageal ulcers Varices, Colitis, Mallory-Weiss tear, Gastric Erosions</p> <p>Thoracic and Pulmonary</p> <p>Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue including: Laryngeal Lesions, Airway obstructions including carcinoma, Polyps and Granulomas, Palliation of obstructing carcinomas of the tracheobronchial tree</p> <p>Gynecology</p> <p>Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis), Intra-uterine treatment of submucous fibroids, benign endometrial polyps, and uterine septum by incision, excision, ablation and or vessel coagulation, Soft tissue excision procedures such as excisional conization of the cervix</p>	<p>Appendectomy, Polyps, Biopsy, Gall Bladder calculi, Biliary/Bile duct calculi, Ulcers, Gastric ulcers, Duodenal ulcers, Non Bleeding Ulcers, Pancreatitis, Hemorrhoids Cholecystectomy, Benign and Malignant Neoplasm, Angiodysplasia, Colorectal cancer, Telangiectasias, Telangiectasias of the Osler-Weber-Renu disease, Vascular Malformation, Gastritis Esophagitis, Esophageal ulcers, Varices, Colitis, Mallory-Weiss tear, Gastric Erosions.</p> <p>Thoracic and Pulmonary</p> <p>Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue including:</p> <p>Laryngeal Lesions, Airway obstructions including carcinoma, Polyps and Granulomas, Palliation of obstructing carcinomas of the tracheobronchial tree</p> <p>Gynecology</p> <p>Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis)</p>	

	<p>ENT</p> <p>Endoscopic endonasal surgery (incision, excision, resection, ablation,vaporization, coagulation and hemostasis of soft tissue) including: Endonasal/sinus Surgery, Partial turbinectomy</p> <p>Polypectomy, Dacryocystorhinostomy, Frontal Sinusotomy, Ethmoidectomy, Maxillary antrostomy, Functional endoscopic sinus surgery, Lesions or tumors of the oral, nasal, glossal, pharyngeal and , laryngeal, Tonsillectomy, Adenoidectomy</p> <p>Dermatology and Plastic Surgery</p> <p>Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, dermatologic and aesthetic surgical procedures including: Basal Cell Carcinomas, Lesions of skin and subcutaneous tissue</p> <p>Skin tags, Plantar warts</p> <p>General Surgery</p> <p>Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: Cholecystectomy, Lysis of adhesion, Appendectomy</p> <p>Biopsy, Skin incision, Tissue dissection, Excision of external tumors and lesions, Complete or partial resection of internal organs, tumors and lesions, Mastectomy, Hepatectomy</p>	<p>Intra-uterine treatment of submucous fibroids, benign endometrial polyps, and uterine septum by incision, excision, ablation and or vessel coagulation</p> <p>Soft tissue excision procedures such as excisional conization of the cervix</p> <p>ENT</p> <p>Endoscopic endonasal surgery (incision, excision, resection, ablation,vaporization, coagulation and hemostasis of soft tissue) including:</p> <p>Endonasal/sinus Surgery, Partial turbinectomy, Polypectomy</p> <p>Dacryocystorhinostomy, Frontal Sinusotomy, Ethmoidectomy, Maxillary antrostomy, Functional endoscopic sinus surgery, Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal, Tonsillectomy, Adenoidectomy</p> <p>Dermatology and Plastic Surgery</p> <p>Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, dermatologic and aesthetic surgical procedures including:</p> <p>Basal Cell Carcinomas, Lesions of skin and subcutaneous tissue, Skin tags, Plantar warts</p> <p>General Surgery</p> <p>Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization,</p>	
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Specifications	Patriot Duo (K251824)	Patriot 1 (K162334)	Comparison
	<p>Pancreatectomy, Splenectomy, Thyroidectomy, Parathyroidectomy, Herniorrhaphy, Tonsillectomy, Lymphadenectomy, Partial Nephrectomy, Pilonidal Cystectomy, Resection of lipoma, Debridement of Decubitus Ulcer, Hemorrhoids, Debridement of Stasis Ulcer, Biopsy</p> <p>Arthroscopy</p> <p>Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue), Ablation of soft and cartilaginous tissue in Minimal Invasive Spinal Surgery including: Percutaneous Laser Disc Decompression/Discectomy, Foraminoplasty, Ablation and coagulation of soft vascular and non vascular tissue, In minimally invasive spinal surgery</p> <p>Note: <i>The Patriot Duo in CW mode is only cleared for BPH when using over 150 W</i></p>	<p>coagulation and hemostasis) including:</p> <p>Cholecystectomy, Lysis of adhesion Appendectomy, Biopsy, Skin incision, Tissue dissection, Excision of external tumors and lesions, Complete or partial resection of internal organs, tumors and lesions, Mastectomy, Hepatectomy, Pancreatectomy Splenectomy, Thyroidectomy, Parathyroidectomy, Herniorrhaphy, Tonsillectomy, Lymphadenectomy, Partial Nephrectomy, Pilonidal Cystectomy, Resection of lipoma, Debridement of Decubitus Ulcer, Hemorrhoids, Debridement of Stasis Ulcer, Biopsy</p> <p>Arthroscopy</p> <p>Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue) Ablation of soft and cartilaginous tissue in Minimal Invasive Spinal Surgery including:</p> <p>Percutaneous Laser Disc Decompression/Discectomy, Foraminoplasty, Ablation and coagulation of soft vascular and non vascular tissue In minimally invasive spinal surgery</p> <p>Note: <i>The Patriot 1 is only cleared for BPH when using over 150 W</i></p>	
Laser Medium:	Tm:Fiber	Tm:Fiber	Same
Wavelength:	1930 – 1950 nm	1940 nm	Same

Specifications	Patriot Duo (K251824)	Patriot 1 (K162334)	Comparison
Power to Tissue:	30 to 200 Watts	10 to 200 Watts	Within Range
Operating Modes:	Continuous (CW)	Continuous (CW)	Same
Pulsed Mode:	CW	CW	Same
Beam Delivery:	200 - 1000 micron and side-fire fibers. Specialty fibers also available	200 - 1000 micron fibers. Specialty fibers also available	Same
Aiming Beam:	520 nm Green diode power adjustable 0-5 mW	450 nm Blue diode adjustable	Similar
Electrical Supply:	220V~ at 5000VA 50/60 Hz	230 VAC, 2.4 kVA , 50/60 Hz,	Similar
Cooling:	Closed cycle, internal	Closed cycle, internal	Same
Dimensions:	H: 45.5 W: 22.5 L: 44	H: 35.3 W: 19.8 L: 29.3	Similar
Weight:	Approx. 350 lbs	Approx. 300 Pounds	Similar

Technological Differences:

Power to Tissue: The power to tissue for the subject device is 30-200 W, while the predicates is 10-200 W. Even though there is a difference, our power is within the range of the predicate, therefore, there are no safety concerns.

Comparison with predicate - Quasi CW Mode

Specification	Patriot Duo (K251824)	SOLTIVE™ Premium (K183647)	Comparison
Indications for Use	<p>The Patriot Duo in the Quasi-CW (SuperPulse) mode is intended for:</p> <p>Urology</p> <p>Ablation of Benign Prostatic Hypertrophy (BPH), Laser Resection of the Prostate (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.</p>	<p>The SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™ 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.</p> <p>Urology</p> <ul style="list-style-type: none"> •Ablation of Benign Prostatic Hyperplasia (Hypertrophy) [BPH] •Laser Resection of the Prostate (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 	Similar

	<p>Lithotripsy and Percutaneous Urinary Lithotripsy Indications</p> <p>Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate dehydrate stones.</p> <p>Gastroenterology</p> <p>Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including:</p> <p>Appendectomy, Polyps, Biopsy, Gall Bladder calculi, Biliary/Bile duct calculi, Ulcers, Gastric ulcers, Duodenal ulcers, Non Bleeding Ulcers, Pancreatitis, Haemorrhoids, Cholecystectomy, Benign and Malignant Neoplasm, Angiodysplasia, Colorectal cancer, Telangiectasias, Telangiectasias of the Osler-Weber-Renu disease, Vascular Malformation, Gastritis, Esophagitis, Esophageal ulcers, Varices, Colitis, Mallory-Weiss tear, Gastric Erosions</p> <p>Gynecology</p> <p>Open and laparoscopic</p>	<p>Lithotripsy and Percutaneous Urinary Lithotripsy Indications</p> <ul style="list-style-type: none"> •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 <p>Gastroenterology</p> <p>Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including:</p> <ul style="list-style-type: none"> •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 •Haemorrhoids •Mallory-Weiss tear •Cholecystectomy •Gastric Erosions •Benign and Malignant Neoplasm <p>Gynecology</p> <p>Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue</p>	
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	gynecological surgery (incision, resection, ablation, vaporization, coagulation and hemostasis) of the soft tissue.		
Laser Classification:	Class 4	Class 4	Same
Laser Type:	Thulium Fiber Laser	Thulium Fiber Laser	Same
Wavelength:	1930 – 1950 nm	1920 nm – 1960 nm	Same
Laser Energy:	0.025 J – 6.0 J	0.025 J – 6 J	Within Range
Laser Frequency:	1 Hz – 2,400 Hz	1 Hz – 2,400 Hz	Same
Average Power:	2 W – 60 W adjustable $\pm 20\%$	2 W – 60 W adjustable	Same
Pulse Duration:	200 μ s and up to 50 ms	200 μ s – 50 ms	Same
Fiber Delivery:	200 - 1,000 micron and Side-Fire	200 - 1,000 micron	Same
Aiming Beam:	520 nm Green power adjustable 0-5 mW	Green, 500 – 550 nm, power adjustable 0-5 mW	Similar
Product Category:	Surgical laser for medical use	Surgical laser for medical use	Same
Class of Medical Device Directive:	Class IIb	Class IIb	Same
Electrical requirements:	230V~ at 3000VA 50/60 Hz	100-240V~ at 1200VA 50/60 Hz	Similar
Dimensions H x W x D:	45.5 x 22.5 x 44 inches	25.5 x 37.0 x 56.0 inches	Similar
Weight:	Approx. 350 lbs	73 lbs	Similar
Laser Cooling System:	Closed cycle, internal, air	Air	Same
Protection against electric shock:	Class 1 / Type BF	Class 1 / Type BF	Same

Note: For Lithotripsy and Percutaneous Urinary Lithotripsy Indications, the SOLTIVE™ Premium is indicated for “Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed”. This indication is not included in for the Patriot Duo; however, the indications for use of the Patriot Duo still fall within the range of the SOLTIVE™ Premium predicate device. Therefore, this difference does not impact safety nor effectiveness of the device.

Technological Differences:

Wavelength: The wavelength for the subject device is 1930 – 1950 nm, while for the predicate it’s 1920 nm – 1960 nm. In both cases the center frequency is identical; both lasers are 1940 nm lasers, therefore, there are no safety concerns.

Aiming Beam: The aiming beam for the predicate and the subject device are identical in the power class and center frequency, therefore, there are no safety concerns.

Conclusion

Based upon the intended use and known technical information provided in this pre-market notification, the device is substantially equivalent to the predicate Patriot 1 Family of Lasers and the SOLTIVE™ Premium SuperPulse Laser, as it shares similar intended uses, technological characteristics, and principles of operation. Comprehensive non-performance testing demonstrated that any technological differences in optical and energy outputs are clinically insignificant. Coupled with verification testing results showing equivalence and evidence of safe and effective operation, it has been determined that the Patriot Duo Laser and its associated accessories meet all necessary requirements and specifications without raising new safety or effectiveness concerns.