DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 27, 2017

U.S. Laser Worx
Frank Ford
CEO
13423 Blanco Rd #162
San Antonio, Texas 78216

Re: K162334
Trade/Device Name: U.S. Laser Worx Patriot 1 Family of Lasers
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: February 9, 2017
Received: February 13, 2017

Dear Mr. 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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Indications for Use Statement

510(k) Number (if known): K162334

Device Name: Patriot 1 Family of Lasers and Accessories

Indications for Use:

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 encountered in urology, gastroenterology, thoracic and pulmonary, gynecology, ENT, dermatology and plastic surgery general surgery and arthroscopy.

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, Uretheral Tumors.
Ablation of Benign Prostatic Hypertrophy (BHP),
Transurethral incision of the prostate (TUIP)
Laser Resection of the Prostrate (HoLRP)
Laser Enuculeation of the Prostate (HoLEP)
Laser Ablation of the Prostate (HoLAP)
Condylomas
Lesions of external genitalia

Prescription Use: X AND/OR Over the Counter Use: _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODpE)

Indications for Use Statement (continued)

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
Pancreatitas
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

Prescription Use: __X____ AND/OR Over the Counter Use: _____
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Concurrence of CDRH, Office of Device Evaluation (ODpE)

Indications for Use Statement (continued)

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

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Concurrence of CDRH, Office of Device Evaluation (ODpE)

Indications for Use Statement (continued)

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

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Concurrence of CDRH, Office of Device Evaluation (ODpE)

Indications for Use Statement (continued)

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 Statis Ulcer
Biopsy

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Concurrence of CDRH, Office of Device Evaluation (ODpE)

Indications for Use Statement (continued)

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

Note: The Patriot 1 180 and 200 are only cleared for BPH when using over 150 W

Prescription Use: __X____ AND/OR Over the Counter Use: _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODpE)

510K SUMMARY

Title:	U. S. Laser Worx, Inc. Patriot 1 Family of Lasers and Accessories
Submitter:	U. S. Laser Worx, Inc.
Contact:	Timothy J. Shea 189 Winding Oaks Lane Oviedo, FL 32765 Phone: 407-590-2050 Email: tsheabo@aol.com
Date Prepared:	August 6, 2016
Device Trade Name:	Patriot 1 Family of Lasers and Accessories
Common Name:	Tm:Fiber Laser
Classification Name	21 CFR Part 878.4810 Laser Surgical instrument for use in general and plastic surgery as well as Dermatology
Predicate Devices:	AllMed Systems, Inc. Revolix 120 (K07046) and the Quanta System Cyber Tm 120, Tm 150, Tm 180 and the Tm 200 (K131081)
Review Panel:	General and Plastic Surgery (GEX)
PRODUCT CODE:	GEX

Device Description: **General Description- Thulium Laser/ Patriot 1 family of lasers**

Indications for use

Indications for Use Statement:

510(k) Number (if known): K162334

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Biliary/Bile duct calculi
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Pancreatitas
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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
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Concurrence of CDRH, Office of Device Evaluation (ODpE)

Indications for Use Statement (continued)

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Dacryocystorhinostomy
Frontal Sinusotomy
Ethmoidectomy
Maxillary antrostomy
Functional endoscopic sinus surgery
Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal
Tonsillectomy
Adenoidectomy

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Concurrence of CDRH, Office of Device Evaluation (ODpE)

Indications for Use Statement (continued)

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Concurrence of CDRH, Office of Device Evaluation (ODpE)

Indications for Use Statement (continued)

General Surgery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

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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 Statis Ulcer
Biopsy

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Concurrence of CDRH, Office of Device Evaluation (ODpE)

Indications for Use Statement (continued)

Arthroscopy

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Concurrence of CDRH, Office of Device Evaluation (ODpE)

SPECIFICATIONS

Patriot 1 Family of Lasers Technical Specifications

Laser Type:	Tm:Fiber
Wavelength:	1.94 microns
Power to Tissue:	5 to 120, 150, 180, 200 Watts
Operating Modes:	Continuous
Beam Delivery:	400, 600 and 1000 micron fibers. Specialty fibers also available.
Aiming Beam:	450, Blue Diode, Adjustable
Electrical Supply:	230 VAC, 2.4 kVA, 50/60 Hz
Cooling:	Closed cycle, internal
Dimensions:	H: 35.3 L: 29.3 W: 19.8
Weight:	TBD Pounds

General Device Description (unmodified predicate devices vs new modified devices):

The U. S. Laser Worx Family of lasers are surgical instrument for use in general and plastic surgery and in dermatology (GEX).

The Patriot 1 Family of lasers are installed with a single Tm:Fiber Laser Source with CW emission at 1.94 microns with adjustable power from 5 W to the maximum output power (as given below). The laser radiation is delivered to the tissue to be treated through fiber optics.

The Patriot 1 Family (that includes 120, 150, 180 and the 200) and its accessories are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery and Arthroscopy.

Note: the Patriot 1 180 and 200 are only approved for the treatment of BPH when used at power levels greater than 150W.

The Patriot 1 Family has the following models (and related main characteristics):

Patriot 1 120 5 to 120 Watts to tissue

Patriot 1 150 5 to 150 Watts to tissue

Patriot 1 180 5 to 180 Watts to tissue

Patriot 1 200 5 to 200 Watts to tissue

All models of the Patriot 1 Family share the same structure, the same components and the same software. The differentiation of the models derives only from the factory set of the maximum output power of the laser resonator.

SUBSTANTIAL EQUIVALENCE SUMMARY

Company/ Specifications	US. Laser Worx, Inc. Patriot 1 Family of Lasers	AllMed Systems Inc. Revolix 120	Quanta System SPA Cyber Tm 120, 150, 180 and 200
Concurrence: 510(k) Number:	Pending	K070476	K131081
Laser Medium:	Tm:Fiber	Tm:Fiber	Tm:Fiber
Wavelength:	1.94 microns	2.01 microns	2.01 microns
Power to Tissue:	5 to 120, 150, 180 and 200 Watts	5 to 120 Watts	1 to 120, 150, 180 and 200 Watts
Operating Modes:	Continuous	Continuous and Pulsed	Continuous and Pulsed
Pulsed Mode:	CW	50 ms to CW	10 to 1,000 ms, CW
Beam Delivery:	400, 600 and 1000 micron fibers. Specialty fibers also available	200, 400, 600 and 1000 micron fibers. Specialty fibers also available	600, 800 and 1000 micron fibers. Specialty fibers also available
Aiming Beam:	450 nm, Blue Diode, adjustable	635 nm Red Diode, 1 mW Adjustable	635 nm Red Diode adjustable
Electrical Supply:	230 VAC, 30 Amps, 50/60 Hz,	230 VAC, 2.4 kVA, 50/60 Hz	200-240, 50/60 Hz, 16 Amps
Cooling:	Closed cycle, internal	Closed cycle, internal	Closed cycle, internal
Dimensions:	H: 35.3” W: 19.8” L: 29.3”	H: 38” W: 17” L: 35”	H: 43.3” W: 21.6” L: 29.5”
Weight:	TBD Pounds	330 Pounds	352 Pounds

NOTE: The Patriot 1 180 and 200 are only cleared for BPH when using over 150 Watts

Summary: From a design and clinical perspective, the predicate and candidate laser devices, are the same technology and have the same intended uses. Based upon the fact that the devices are extremely similar, the Patriot 1 Family of Lasers and Accessories should not raise any concerns regarding its overall safety and/or effectiveness.

Non-Clinical Performance Data:

Performance Standards: THERE ARE NO PERFORMANCE STANDARDS NECESSARY/REQUIRED FOR THIS DEVICE.

IEC safety standards met:

60601-1 ED 3.1(2012)

60601-1-2:2014 4th Ed

60601-2-22 Ed 3.1(2012)

60601-1:2005

60601-1 ED3 (2007) AMENDMENT 1(2013)

60601-1:14(2014) –CANADA

60825-1 2007

ADDITIONALLY, WE PERFORMED NUMEROUS BENCH TESTS INVOVING POWER VERIFICATIONS, MEASUREMENTS, ACCURACY OF SOFTWARE AND ENERGY TRANSMISSION