K110941

FEB 19 2013

Attachment V

510(k) Summary

1.General Information

Submitter:	AllMed Systems Inc. 9232 Klemetson Drive Pleasanton CA 94588
Phone:	925-468-0433
Fax	925-399-5984
Contact Person	Peter Allen
Date Prepared	24th March 2011

2. Names

Device Name	Revolix Family of Laser Systems including the RevoLix Jr 30, RevoLix Jr 50 RevoLix 160 and RevoLix 200
Common Name	2.01micron Laser System
Classification Name	Laser Surgical Instrument and accessories

3. Predicate Device

RevoLix Jr, RevoLix 120 watt and Quanta Cyber TM 150

4. Product Description

The RevoLix Family of diode pump solid state (that include the RevoLix Jr 30, RevoLix Jr 50, RevoLix 160 and RevoLix 200) are part of a family of surgical laser systems operating at a wavelength of 2.01 micron. The purpose of these lasers is to ablation, coagulation, dissection and resection of soft tissue. The laser is designed for open surgery, laparoscopic surgical applications and procedures in an aqueous and non-aqueous media. The laser power is delivered via standard silica laser fibers. The distal tip is guided by a hand piece, endoscopic or laparoscopic surgical instrument.

It consists of:

Laser Console with Internal Computer
Control Panel and Display
A fiber optic delivery system
Footswitch

5. Indications for Use

The RevoLix Jr 30, RevoLix Jr 50, RevoLix 160 and RevoLix 200 laser systems and their fiber optic delivery system 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

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 and Ureteral
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

Note: The RevoLix 160 and 200 are only approved for the treatment of BPH when used at power levels greater than 120 watts

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

Thoracic and Pulmonary

Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue

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 hemostasisof 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
- 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

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

6. Rationale for Substantial Equivalence

The Revolix Jr 30, RevoLix Jr 50, RevoLix 160 and RevoLix 200 laser systems and their fiber optic delivery devices share the same intended use, indications for use, similar design features and functional features and therefore are substantially equivalent to the RevoLix Jr, RevoLix 120 and Quanta Cyber TM 150.

Testing and Clinical Evaluation.

All necessary bench testing was conducted on the proposed family of RevoLix lasers to support a determination of substantial equivalence to the predicate device. The depth of thermal injury and coagulation were measured and compared to the RevoLix 120 and did not show significant differences. The ablation depth was also measured and found to be of comparable depth, with an adjustment in the translation speed depended on the power level. Other tissue effects such as carbonization were also found to be comparable. All clinical data provided in this submission supporting the RevoLix 200 at a setting of 200 watts is provided ONLY for the indication of use in the treatment of BPH.

7. Conclusion

The Revolix Jr 30, RevoLix Jr 50, RevoLix 160 and RevoLix 200 Laser Systems with fiber optic delivery devices was found to be safe and effective and therefore substantially equivalent to the predicate surgical laser systems and delivery devices.

Note: The RevoLix 160 and 200 are only approved for the treatment of BPH when used at power levels greater than 120 watts

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

AllMed Systems, Incorporated
% Mr. Peter Allen
495 Main Street
Wilbraham, Massachusetts 01095

February 19, 2013

Re: K110941
Trade/Device Name: RevoLix Jr 30, RevoLix Jr 50, RevoLix 160 and RevoLiz 200
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: March 24, 2011
Received: December 31, 2012

Dear Mr. Allen:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K110941**

Device Name: RevoLix Jr 30, RevoLix Jr 50, RevoLix 160 and RevoLix 200

Indications For Use:

The Revolix Jr 30, RevoLix Jr 50, RevoLix 160 and RevoLix 200 laser systems and their fiber optic delivery system 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

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 and Ureteral 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

Note: The RevoLix 160 and 200 are only approved for the treatment of BPH when used at power levels greater than 120 watts

Neil R Ogden -S
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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K110941

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 (ODE)

Indications for Use

510(k) Number: **K110941**

Device Name: RevoLix Jr 30, RevoLix Jr 50, RevoLix 160 and RevoLix 200

Indications For Use:

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

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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K110941

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 (ODE)

Indications for Use

510(k) Number: **K110941**

Device Name: RevoLix Jr 30, RevoLix Jr 50, RevoLix 160 and RevoLix 200

Indications For Use:

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

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

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510(k) Number K110941

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Indications for Use

510(k) Number: **K110941**

Device Name: RevoLix Jr 30, RevoLix Jr 50, RevoLix 160 and RevoLix 200

Indications For Use:

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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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K110941

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Indications for Use

510(k) Number: **K110941**

Device Name: RevoLix Jr 30, RevoLix Jr 50, RevoLix 160 and RevoLix 200

Indications For Use:

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
Skin incision
Tissue dissection
Excision of external tumors and lesions
Complete or partial resection of internal organs, tumors and lesions
Mastectomy
Hepatectomy

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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K110941

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
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Indications for Use

510(k) Number: **K110941**

Device Name: RevoLix Jr 30, RevoLix Jr 50; RevoLix 160 and RevoLix 200

Indications For Use:

Pancreatectomy
Splenectomy
Thyroidectomy
Parathyroidectomy
Herniorrhaphy
Tonsillectomy
Lymphadenectomy
Partial Nephrectomy
Pilonidal Cystectomy
Resection of lipoma
Debridement of Decubitus Ulcer
Hemorrhoids
Debridement of Statis 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.

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(Division Sign-Off) for MXM
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