MAR 1 8 2014

Attachment V

510(k) Summary K132 975

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	17th September 2013

2. Names

Device Name	Sphinx Jr Laser
Common Name	laser surgical instrument
Classification Name	79GEX
CFR Reference	21 CFR 878.4810 Laser surgical instrument for use in general, plastic and dermatological surgery

3. Predicate Device

Sphinx Family of lasers, and Lumenis - Versapulse

4. Product Description

The Sphinx Jr. system is a surgical laser system operating at a wavelength of 2.1 micron. The purpose of the laser is the ablation, coagulation, dissection and resection of soft tissue. The laser is designed for open surgery and surgical applications in aqueous media and non aqueous medium. The laser power is delivered via standard silica laser fibers. The distal tip is guided by a handpiece endoscopic surgical instrument or similar approved device

It consists of:

Laser Console with Internal Computer
Control Panel and Display
Operating Software
Fiber port
Footswitch

5. Indications for Use

The Sphinx Jr laser system is 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, Urinary Lithotripsy, Gasteroenterology, Arthroscopy, Discetomy Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery and General Surgery.

<u>Urology</u>

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)
Holmium Laser Resection of the Prostrate (HoLRP)
Holmium Laser Enuculeation of the Prostate (HoLEP)
Holmium laser Ablation of the Prostate (HoLAP)
Condylomas
Lesions of external genitalia

Lithotripsy and Percutaneous Urinary Lithotripsy

Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate dehydrate stones.
Endoscopic fragmentation of kidney calculi
Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed.

<u>Gasteroenterlogy</u>

Open and endoscopic gasteroenterlogy 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

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue) in small and large joints of the body, excluding the spine but including:

Ligament and tendon Release
Contouring and sculpting of articular surfaces
Capsulectomy in the Knee
Chondreplasty in the Knee
Debridement of inflamed synovial tissue
Chondromalacia Ablation
Chondromalacia and tears
Plica Removal
Meniscectomy
Loose Body Debridement
Lateral retinecular release

Ablation of soft, cartilaginous and bony tissue in Minimal Invasive Spinal Surgery including

Percutaneous Laser Disc Decompression/Discectomy of the L4-5 and L5-S1 lumbar discs, including Foraminoplasty
Percutaneous Cervical Disc Decompression/Discectomy
Percutaneous Thoracic Disc Decompression/Discectomy

Thoracic and Pulmonary

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

Gynecology

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

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue and cartilage) including:

- Endonasal/sinus Surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal Sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery

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
- Lesions of skin and subcutaneous tissue
- Port Wine Stains
- Papillomas

General Surgery

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

- Appendectomy
- Skin incision
- Excision of external and internal lesions
- Complete of partial resection of internal organs, tumors and lesions
- Biopsy

Safety and Effectiveness of the Sphinx Jr.

Rationale for Substantial Equivalence

The Sphinx Jr systems with 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 Sphinx Family of Lasers K033437 and Versapulse K011703.

Non Clinical Testing

All necessary Software and EMC testing was conducted on the proposed Sphinx Jr to support a determination of safety to the predicate devices.

Performance

Since the specification and performance of the Sphinx laser system and the predicate devices are the same, it is suggested that preclinical performance data is not required

Conclusion

The Sphinx Jr 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

March 18, 2014

AllMed Systems, Inc.
Peter N. Allen
9232 Klemetson Drive
Pleasanton, California 94588

Re: K132975
Trade/Device Name: Sphinx Jr.
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 10, 2014
Received: February 25, 2014

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,

Felipe Aguel

for Binita Ashar, MD, MBA, FACS
Acting Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132975

Device Name
Sphinx Jr Laser System

Indications for Use *(Describe)*

The Sphinx Jr. laser system is intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft and hard tissue in use in medical specialties including:

Urology, Urinary Lithotripsy, Gasteroenterology, Arthroscopy, Discectomy, Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery and General Surgery

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:
Urethral Strictures
Bladder Neck Incisions
Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors.
Ablation of Benign Prostatic Hypertrophy (BHP)
Resection of the Prostrate
Condylomas
Lesions of external genitalia

Lithotripsy and Percutaneous Urinary Lithotripsy
Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi
Endoscopic fragmentation of kidney calculi
Treatment of steinstrasse when guide wire cannot be passed

Gasteroenterlogy

Open and laparoscopic gynecological 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
Pancreatitas
Hemorrhoids
Cholecystectomy
Benign and Malignant Neoplasm
Angiodysplasia

Colorectal cancer
Telangiectasias
Vascular Malformation
Gastritis
Esophagitis

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue) excluding the spine but including:

Ligament and tendon Release
Contouring and sculpting of articular surfaces
Capsulectomy in the Knee
Chondreplasty in the Knee
Debridement of inflamed synovial tissue
Chondromalacia Ablation
Chondromalacia and tears
Plica Removal
Meniscectomy
Loose Body Debridement

Ablation of soft, cartilaginous and bony tissue in Minimal Invasive Spinal Surgery including

Percutaneous Laser Disc Decompression/Discectomy
Foraminoplasty

Pulmonary

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

Gynecology

Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:
Outer female genitals
Ablation of condilomata and genital warts
Inner genitalia
Endometrium ablation
Treatment of Uterine polyps
Treatment of endometriosis

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue) including:

Endonasal/sinus Surgery
Partial turbinectomy
Polypectomy
Dacryocystorhinostomy
Ethmoidectomy

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
Lesions of skin and subcutaneous tissue

General Surgery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:
Appendectomy
Skin incision
Excision of external and internal lesions
Complete of partial resection of internal organs, tumors and lesions
Biopsy

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.03.18 13:44:01 -04'00' For BSA

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