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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	27th October 2003

2. Names

Device Name	Sphinx
Common Name	2.1micron Laser System
Classification Name	Laser Surgical Instrument and accessories

3. Predicate Device

Lumenis – Holmium VersaPulse Power Suite Holmiun Laser
Trimedyne - OmniPulse Max 80 Watt Holmium Laser System

4. Product Description

The Sphinx 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. The laser power is delivered via standard silica laser fibers. The distal tip is guided by a handpiece or endoscopic surgical instrument.

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It consists of:

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

5. Indications for Use

The Sphinx laser system and its 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, Urinary Lithotripsy, Gasteroenterology, Arthroscopy, Discetomy 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 (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.

Gasteroenterlogy

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

Appendectomy
Polyps
Biopsy

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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
Countouring 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

Pulmonary

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

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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

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6. Rationale for Substantial Equivalence

The Sphinx laser system 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 Lumenis VersaPulse PowerSuite 100 watt Holmium Laser, and the Trimedyne OmniMax 80 watt Holmium Laser.

7. Conclusion

The Sphinx Laser System with fiber optic delivery devices were found to be substantially equivalent to similar currently marketed and predicate surgical laser systems and delivery devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 0 2004

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

Re: K033437
Trade/Device Name: Sphinx
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 26, 2003
Received: October 30, 2003

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K033437

Device Name: Sphinx

Indications For Use:

The Sphinx laser system and its 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, Urinary Lithotripsy, Gasteroenterology, Arthroscopy, Discetomy 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 (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

Prescription Use ✓ 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: K033437

Device Name: Sphinx

Indications For Use:

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.

Gasteroenterlogy

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

Prescription Use ✓ 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: K033437

Device Name: Sphinx

Indications For Use:

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
Countouring and sculpting of articular surfaces
Capsulectomy in the Knee
Chondreplasty in the Knee
Debridement of inflamed synovial tissue
Chondromalacia Ablation
Chondromalacia and tears

Prescription Use ✓ 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: K033437

Device Name: Sphinx

Indications For Use:

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

Pulmonary

Open and endoscopic pulmonary 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

Prescription Use ✓ AND/OR Over-The-Counter Use _____
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number: K033437

Device Name: Sphinx

Indications For Use:

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

Prescription Use ✓ AND/OR Over-The-Counter Use _____
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number: K033437

Device Name: Sphinx

Indications For Use:

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

Prescription Use ✓ 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)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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