

Attachment V

K070466

510(k) Summary

APR 17 2007

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 16th February 2007

2. Names

Device Name Revolix Duo Laser System

Common Name 2.01micron and 2.1 micron Laser System

Classification Name Laser Surgical Instrument and accessories

3. Predicate Device

Lisa Laser Products – RevoLix Continuous Wave 2 micron Laser
Lisa Laser Products - Sphinx 80 Watt Holmium Laser System

4. Product Description

The RevoLix Duo is a combination of a diode pump solid state laser operating at a wavelength of 2.01 micron and a pulsed flashlamp Holmium laser operating at 2.1 microns. 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.

It consists of:

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

5. Indications for Use

The Revolix Duo continuous wave 2.01 micron 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, Gastroenterology, Arthroscopy, Discetomy, Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery and General Surgery

Continuous Wave 2.01 micron Laser

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 Hyperplasia (BHP),
- Transurethral incision of the prostate (TUIP)
- Holmium Laser Resection of the Prostrate (HoLRP)
- Holmium Laser Enucleation of the Prostate (HoLEP)
- Holmium laser Ablation of the Prostate (HoLAP)
- Condylomas
- 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

Laryngeal Lesions
Airway obstructions including carcinoma
Polyps and Granuloma
Palliation of obstructing carcinoma 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 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 or 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 Revolix Duo pulsed Holmium 2.1 micron 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 and hard tissue in use in medical specialties including: Urology, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discetomy Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery and General Surgery.

Holmium Laser pulsed 2.1 micron

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)
- Holmium Laser Resection of the Prostrate (HoLRP)
- Holmium Laser Enucleation 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.

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

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
- Chondroplasty in the Knee
- Debridement of inflamed synovial tissue
- Chondromalacia Ablation
- Chondromalacia and tears
- Plica Removal
- Meniscectomy
- Loose Body Debridement
- Lateral retinacular 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

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 or partial resection of internal organs, tumors and lesions
- Biopsy

6. Rationale for Substantial Equivalence

The Revolix Duo 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 Lisa Laser Products RevoLix continuous wave 2 micron laser , and the Lisa Laser Products Sphinx 80 watt Holmium Laser

7. Conclusion

The Revolix Duo 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

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

APR 17 2007

Re: K070466

Trade/Device Name: Revolix Duo
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: April 6, 2007
Received: April 9, 2007

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.

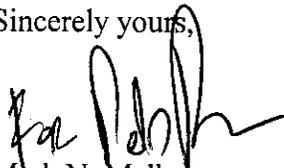
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Mr. Peter Allen

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
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:

Device Name: Revolix Duo

Indications For Use:

The Revolix Duo continuous wave 2.01 micron 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, Gastroenterology, Arthroscopy, Discetomy, Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery and General Surgery

Continuous Wave 2.01 micron Laser

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 Hyperplasia (BHP),

Transurethral incision of the prostate (TUIP)

Holmium Laser Resection of the Prostrate (HoLRP)

Holmium Laser Enucleation of the Prostate (HoLEP)

Holmium laser Ablation of the Prostate (HoLAP)

Condylomas

Lesions of external genitalia

Gastroenterology

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

Appendectomy

Polyps

Biopsy

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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:

Device Name: Revolix Duo

Indications For Use:

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

Laryngeal Lesions
Airway obstructions including carcinoma
Polyps and Granuloma
Palliation of obstructing carcinoma of the tracheobronchial tree

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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:

Device Name: Revolix Duo

Indications For Use:

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 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 or 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

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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:

Device Name: Revolix Duo

Indications For Use:

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

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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:

Device Name: Revolix Duo

Indications For Use:

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 Revolix Duo pulsed Holmium 2.1 micron 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 and hard tissue in use in medical specialties including: Urology, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery and General Surgery.

Holmium Laser pulsed 2.1 micron

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)
Holmium Laser Resection of the Prostrate (HoLRP)

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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:

Device Name: Revolix Duo

Indications For Use:

Holmium Laser Enucleation 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.

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

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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:

Device Name: Revolix Duo

Indications For Use:

- 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

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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:

Device Name: Revolix Duo

Indications For Use:

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

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:

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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:

Device Name: Revolix Duo

Indications For Use:

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 or partial resection of internal organs, tumors and lesions
Biopsy



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number

 K070466

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)