K 121570

510(k) Auriga QI
Summary (Section 5)

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510(k) summary of safety and effectiveness information according 21 CFR Part 807.87(h)

JAN 16 2013

1. General Information:
   a. Applicant: StarMedTec GmbH
   Kreuzstrasse 22
   82319 Starnberg
   Germany
   +49815126861-0 (phone)
   +49815126861-35 (fax)

   b. Contact: Gregor Weidemann
   c. Date Prepared: May 24, 2012

2. Names:
   a. Device Name: Auriga QI
   b. Common Name: Auriga QI
   c. Classification Name: Laser instrument, surgical, powered
   d. Product code: GEX

3. Predicate Device:
   StarMedTec GmbH – Auriga XL (510(k) Number: K111475)

4. Product Description:
   The Auriga QI is a holmium laser system, which emits laser radiation with a wavelength of approximately 2,1 µm. Optical laser power is transferred via an optical application fiber. The indications are lithotripsy, dissection, ablation, resection and coagulation of tissue.
   The laser system consists of:
   - laser system including control panel (user interface)
   - foot switch
   - application fiber

5. Indications for use:
   The Auriga QI laser system including a fiber optic delivery system is intended to be used in surgical procedures such as open, laparoscopic and endoscopic, to perform incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in medical specialities including:
   Urology, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy, Pulmonary, Gynaecology, ENT, Dermatology, Plastic Surgery and General Surgery.

   Urology

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

   - Strictures of urethra and ureter
   - Bladder Neck Incisions (BNI)

- Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors
- Ablation of Benign Prostatic Hyperplasia (BPH)
- Transurethral incision of prostate (TUIP)
- Holmium Laser Resection of the prostate (HoLRP)
- Holmium Laser Enucleation of the prostate (HoLEP)
- Holmium Laser Ablation of the prostate (HoLap)
- Bladder/Renal calculi (Lithotripsy)
- Condylomas
- Lesions or external genitalia
- Lithotripsy
- 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 gastroenterological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder Calculi (Lithotripsy)
- Biliary/Bile duct calculi (Lithotripsy)
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non bleeding ulcers
- Pancreatitis
- Hemorrhoids
- Cholecystectomy
- Benign and malignant neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of 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 crtilaginous tissue) in small and large joints of the body excluding the spine but including:

- Ligament and tendon Release
- Contouring and sculpting of articular surfaces
- Capsulectomie in the knee
- Chondreoplasty in the knee
- Debridement of inflamed synovial tissue
- Chondromalacia ablation
- Chondtromalcia and tears
- Plica removal
- Meniscectomy
- Loose body debridement
- Lateral retineacular 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 forminoplasty
- Percutaneous cervical disc decompression/discectomy
- Percutaneous thoracic disc decompression/discectomy

Thoracic and Pulmonary

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

Gynaecology

Open and endoscopic/laparoscopic gynaecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis).

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 sinustomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery

Dermatology and Plastic Surgery

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue, mucosal tissue, fatty tissue and cartilaginous tissue in therapeutic plastic, dermatologic and aesthetic surgical procedures including:

- Basal Cell Carcinomas
- Lesion 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
- Biopsy
- Skin incision
- Excision of external tumours and lesions
- Complete or partial resection of internal organs, tumours, lesions

6. Performance testing:

The Auriga QI is tested according to following standards:

ISO 14971:2006
IEC 60601-1:2005 (DIN EN 60601-1:2006)
IEC 60601-1-2:2007 (DIN EN 60601-1-2:2007-12)
IEC 60601-1-6:2006 (DIN EN 60601-1-6:2007) / IEC 62366:2007 (DIN EN 62366:2008)
IEC 60601-2-22:2005
IEC 60825-1:2007 (DIN EN 60825-1:2007)
IEC 62304:2006 (DIN EN 62366:2006)
The device also complies with European Medical Device 93/42/EEC + Amendment 2007/47/EC

7. Performance data

Laboratory testing was conducted to verify and validate that the Auriga QI met all design specifications and is substantially equivalent to the predicate device.
Clinical data: No clinical information is required.

8. Conclusion:

The Auriga QI is as effective and safe as the predicate device. The Auriga QI is substantially equivalent to the cited legally marketed predicate device.

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

StarMedTec GmbH
% Mr. Gregor Weidemann
Director, Regulatory Affairs
Kreuzstrasse 22
Starnberg, Germany 82319

January 16, 2013

Re: K121570
Trade/Device Name: Auriga QI
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: December 18, 2012
Received: December 21, 2012

Dear Mr. Weidemann:

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,

Peter D. Rumm -S

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

Enclosure

510(k) Auriga QI
Indication for Use Statement (section 4)

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Indications for Use

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Prescription Use___X____ AND/OR Over-The-Counter-Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Neil R Ogden
2013.01.15 16:25:29 -05'00'

(Division Sign-Off) for mxm
Division of Surgical Devices
510(k) Number K121570

510(k) Auriga QI
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Dermatology and Plastic Surgery

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Prescription Use___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter-Use_____ (21 CFR 801 Subpart C)

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Division of Surgical Devices
510(k) Number K121570

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Prescription Use__X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter-Use_____ (21 CFR 801 Subpart C)

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Neil R Ogden
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(Division Sign-Off) for mm
Division of Surgical Devices
510(k) Number K121570

510(k) Auriga QI
Indication for Use Statement (section 4)

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Prescription Use___X____ AND/OR Over-The-Counter-Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.01.15 16:29:10 -05'00'

(Division Sign-Off) for mxm

Division of Surgical Devices

510(k) Number ___K121570____