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5. 510 (k) Summary (21 CFR 807.92)

JUN 28 2011

510 (k) Submitter's Name:
MedArt A/S

Address:
MEDART A/S
Industriholmen 15a
Hvidovre,
Denmark DK-2650

Contact Person:
Joanne Davies,
Regulatory Affairs Manager, Energist Limited
joanne.davies@energist-international.com

Telephone:
+44(0)1792 798768

Fax:
+44(0)1792 762099

Date:
20th January 2010

Device Name:
MedArt® 720

Trade/Proprietary Name:
MedArt® Diode Laser System & Accessories

Classification Name:
Laser surgical instrument for use in general and plastic surgery and in dermatology

Confidentiality Preference:
No preference

Establishment Registration Number:
8021543

510 (K) Type:
Traditional

Class:
2

Panel:
General & Plastic Surgery

Product Code:
GEX

Submission Basis:
New Device

Description of Device:

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The MedArt® 720 laser unit is a Class 4 laser that emits invisible laser radiation. The unit is fed by a diode laser module providing continuous or pulsed wave laser beam operating at a wavelength of 980 nm that is primarily absorbed in melanin, haemoglobin and dark tissue. A limited amount of light is absorbed by water enabling fast increase in irradiated areas leading to effective heating of tissue at low power outputs.

Intended Use:

The MedArt 720 Diode Laser System & Accessories is a prescription only device intended for delivery of laser light to soft tissue in the contact or non-contact mode during surgical procedures, including via endoscopes, introducers, or catheters.

The MedArt 720 Diode Laser System & Accessories is generally indicated for incision, excision, vaporization, ablation, hemostasis, or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery, and cardiothoracic surgery and ophthalmology.

The MedArt 720 Diode Laser System & Accessories is specifically indicated for laser assisted lipolysis

Indications For Use:

Ear Nose, Throat & Oral Surgery	Hemostasis, incision, excision, ablation, coagulation & vaporization of tissue from the ear, nose, throat & adjacent areas including soft tissue in the oral cavity.
Dental Applications	Intraoral and extra-oral soft tissue (including marginal and interdental gingiva and epithclial lining of free gingiva
Arthroscopy	Hemostasis, incision, excision, coagulation, vaporization and ablation of joint tissues during arthroscopic surgery
Gastroenterology	Hemostasis, incision, excision, ablation, coagulation & vaporization of tissue in the upper and lower gastrointestinal tracts and also with endoscopic procedures
General surgery, Dermatology, Plastic Surgery & Podiatry	Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue and dermabrasion
Urology	Excision, vaporization, incision, coagulation, ablation and hemostasis of urological tissues
Gynecology	Ablation, excision, incision, coagulation, hemostasis and vaporization of gynecological tissue

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Neurosurgery	Vaporization, coagulation, excision, incision ablation and hemostasis of soft tissue
Pulmonary Surgery	Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system
Cardiothoraic Surgery	Incision, excision, vaporization, ablation, hemostasis, and coagulation of soft tissue including cardiac tissues
Laser Assisted Lipolysis	Laser Assisted Lipolysis
Opthalmology	The ablation, vaporization, excision, incision, and coagulation of soft tissue in opthalmology

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Predicate Device: K081015

Technological Characteristic Comparison

Characteristic	MedArt® 720	Cerelas D980	Cerelas D980
510 (k)	K110243	K081015	K081015
CFR	878.4810	878.4810	878.4810
Laser Class	4	4	4
Laser Wavelength	980 nm +/- 10 nm	980 nm	980 nm
Output Power	15W	15W	25W
Size	10.9" x 13.0" x 6.0"	7" x 9" x 14"	7"x 15" x16"
	II	II	II
Product Code	GEX	GEX	GEX

- This summary only includes information that is covered in the body of the 510 (k)
- Ths summary does not contain any unsubstantiated labeling claims
- This summary includes summary data only
- This summary does not contain any trade secrets or confidential commercial information
- The summary does not contain any patient identifiction information

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MedArt A/S
% Energist, Ltd.
Ms. Joanne Davies
Clos Llyn Cwm
Swansea, Wales
United Kingdom SA6 8QY

JUN 28 2011

Re: K110243
Trade/Device Name: MedArt® 720
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: June 16, 2011
Received: June 21, 2011

Dear Ms. Davies:

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,

Enid Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110243 Page 1 of 2

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4. Indications for Use Statement

510(k) Number (if known):

Device Name:
MedArt® 720

Intended Use:

(Division Sign-Off)
Division of **Surgical, Orthopedic,** and **Restorative Devices**

510(k) Number K110243

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Neurosurgery	Vaporization, coagulation, excision, incision ablation and

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	hemostasis of soft tissue
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Prescription Use ___X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1/1

Neil R P Ogden for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110243

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