510(k) Summary

K083123

NOV 24 2009

MedArt A/S

MedArt 610 Laser system

This *510(k) summary* is submitted in accordance with the requirements of 21 CFR Part 807.87(h) and Part 807.92.

A. Contact information and device identification:

Date of the summary:	23 November 2009
Submitted by/manufacturer:	MedArt A/S Valseholmen 11-13 2650 Hvidovre, Denmark Tel: + 45 3634 2300 Fax: + 45 3634 2323
Contact person:	Olav Balle-Petersen
Device Trade Name:	MedArt 610
Device Model number:	610.000
Common Name:	Laser treatment system.
Classification name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810).
Device classification:	Class II.
Product code:	GEX
Predicate devices legally marketed to which MedArt A/S claims equivalence:	*Uni-Laser 450P* (K991297) manufactured by ASAH Medico A/S, Denmark. (Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810)).

B. Description of MedArt 610 system:

The MedArt 610 system comprises the following major parts:

- A laser console containing a CO_2 laser module capable of providing a laser beam having a wave-length of 10,600 nm.
- A scanner that is intended to manipulate and place a pulsed beam received from the laser console in a pre-specified pattern on the skin being treated.
- An optical fiber providing a beam path from the laser to the scanner.

C. Indications for Use of MedArt 610 system:

The CO2 laser, model MedArt 610, is intended to be used by physicians in the performance of the following specialities:

The ablation and coagulation of soft tissue in dermatology, plastic and general surgery in the performance of:

- Skin Resurfacing
- Treatment of wrinkles and rhytids
- Treatment of furrows
- Soft tissue ablation

K083123

D. Comparison of MedArt 610 to predicate devices:

Issue/data compared	MedArt 610	Uni-Laser 450P (Asah Medico A/S)
FDA clearance / status	Being submitted (this submission)	K991297
Indications for predicate device		This predicate device under K991297 is cleared for: (copy from 510(k) clearence): **Dermatology, Plastic & General Surgery** The ablation, vaporization, excision, incision and coagulation of soft tissue in dermatology, plastic and general surgery in the performance of: a. Laser Skin Resurfacing b. Treatment of wrinkles, rhytids and furrows c. Blepharoplasty d. Hemorrhoids Ablation and/or vaporization of soft tissue in dermatology and plastic surgery and for the reduction , removal and/or treatment of; • actinic keratosis • skin tags • solar/actinic elastosis • actinic cheilitis • lentigines • uneven pigmentation, dyschromaia • acne scars • surgical scars • keloids • hermangiomes tattoos • telangiectasia • squamous and basel cell carcinoma • spider and epidermal naevi • xanthelasma palpebrarum • syringoma • verrucae and seborrhoecae valugares (warts) **Soft Tissue Dental** Incision and vaporization of soft tissue in dentistry and oral surgery. Applications include;

MedArt®

K083102

Issue/data compared	MedArt 610	Uni-Laser 450P (Asah Medico A/S)
		• gingivectomy- removal of hyperplasisa • gingivoplasty and incisions and exisc-sion • frenectomy • incisional and excisional biopsy • incision and excision o aphous ulcers • exisiosn and ablations of benign and malignant lesions • homeostatis • operculectomy **Podiatry** Laser ablations, vaporization and/or excision of soft tissue in podiatry for • Reduction, removal and/or treatment of verrucae valugares • Matrixectomy **Otorhinolaryngology (ENT)** Laser Incision, excision, ablations and/or va-porization of soft tissue in otorhinlaryngology for the treatment of; • Choanal atresia • Leukoplakia of larynx • Nasal obstructions • UPP • Rhinohyma • Adult and juvenile papillomatosis po-lyps • Rhinophyma • Verruce valares **Gynecology** Laser Incision, excision, ablations and/or va-porization of soft tissue in gynecology for the treatment of; • Cervical intraepithelial neoplasty • Condolyome acuminate • Leukoplakia (vulvar dystrophies) • Vulvar and vaginal intraepithelial neoplasty

K081C

Issue/data compared	MedArt 610	Uni-Laser 450P (Asah Medico A/S)
		Neurosurgery Laser Incision, excision, ablations and/or vaporization of soft tissue in neurology for the treatment of; • Basal tumor-meningioma • Posterior fossa tumors • Peripheral neurectomy • Lipomas/large tumors
Indication comparison		
	Skin resurfacing	Identical application - a
	Wrinkels and rhytids	Identical application – b
	Furrows	Identical application - b
	Soft tissue ablation	Identical application
Technology	The system comprises: a) A laser console containing a CO2 laser module b) A scanner for producing a pattern of light spots on the skin c) a beam delivering system connecting the laser console and the scanner.	The system comprises: a) A laser console containing a CO2 laser module b) A scanner for producing a pattern of light spots on the skin c) a beam delivering system connecting the laser console and the scanner.
Length of beam delivering system	165cm	165cm
Type of beam delivering system	Fiber providing full freedom of movement	Fiber providing full freedom of movement
Wavelength	10,600nm	10,600nm
Max power	0.1 - 12W	0.1-12W
Minimum scanner spot size	Ø400µm	Ø400µm
Max power density (computed as max power divided by minimum scanner spot size)	12/ Ø300µm = 17 kW/cm2	12W / Ø300µm = 17 kW/cm2
Aiming beam	635nm, max 5mW	635nm, max. 2mW

MedArt®

K083123

Issue/data compared	MedArt 610	Uni-Laser 450P (Asah Medico A/S)
Scanning speed (light spots on the skin per second)	0.3-100 Hz	
Time for a full scan	In the range of 1 sec. Actual time is depending on scan pattern chosen	In the range of 1 sec. Actual time is depending on scan pattern chosen
Beam activation	Foot switch	Foot switch

Conclusion:

MedArt 610 applications and indications are evaluated to be within the scope of the previously cleared devices. The same counts for the essential treatment parameters, the protective conditions for the skin during treatment, and the working conditions of the physician.

Based on this side-by-side comparison of the overall performance characteristics of the predicate devices under consideration MedArt A/S concludes that no significant differences exist. The MedArt 610 should not raise any new issues of safety and effectiveness and is judged to be substantially equivalent to the mentioned predicate devices.

_____

(Signature)

Olav Balle-Petersen

(Typed Name)

23-November-2009

(Date)

_____

(Premarket Notification 510(k) Number)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 24 2009

MedArt A/S
% Olav Balle-Petersen
VP, R&D, Innovation, QA
Valseholmen 11-13
2650 Hvidovre, Denmark

Re: K083123
Trade/Device Name: MedArt 610
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: November 24, 2009
Received: November 24, 2009

Dear Olav Balle-Petersen:

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 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.

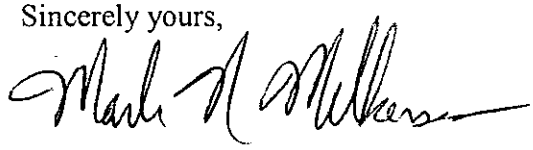
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Sincerely yours,



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

Enclosure

Indications for Use

pg 1 of 1

510(k) Number (if known): _K083123_____

Device Name: _____MedArt 610_____

Indications for Use:

Dermatology, Plastic & General Surgery

The CO2 laser, model MedArt 610, is intended to be used by physicians in the performance of the following specialities:
The ablation and coagulation of soft tissue in dermatology, plastic and general surgery in the performance of:

- Skin Resurfacing
- Treatment of wrinkles and rhytids
- Treatment of furrows
- Soft tissue ablation

Contraindications for MedArt® 610

The MedArt® 610 may not be used for hard tissue dental applications such as tooth enamel, dentin or fillings and other indications not cleared by the FDA.

The system has not been evaluated for safety and effectiveness as a fractionated scanner

Mark N Melkerson

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

510(k) Number K083123

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)