DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2009

Intermedic Arfran, S.A.
% Arizona Glass Tech, Incorporated
Mr. Klaus Sivec
9233 E. Neville Avenue Unit 1128
Meza, Arizona 85212

Re: K053540
Trade/Device Name: INTERmedic Diode Laser Family 810 nm and 980 nm and the delivery accessories that are used with them to deliver, ultrasound and RF energy, including: MULTIDIODE ENDO™ Laser 15, 25, and 50; Surgical 15™, 30™, 50™, 100™, 120™ and SR 15 OFT™, MULTIDIODE PL3D™, ContrAge™, RF ContrAge™ MULTIDIODE SLP ™, MULTIDIODE VARIUS™, VR1000™, MULTIDIODE ODONT™
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: September 6, 2006
Received: August 25, 2006

Dear Mr. Sivec:

This letter corrects our substantially equivalent letter of September 6, 2006.

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

Sincerely yours,

Mark N. Melkerson, PhD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Statement of Indication for Use

510(k) Number: **K503540**

Device Name: INTERmedic Diode Laser Family 810nm and 980nm and the delivery accessories that are used with them to deliver, ultrasound and RF energy, including: MULTIDIODE ENDO™ laser 15, 25 and 50; Surgical SERIES 15™, 25™, 50™, 100™, 120™, OFT™; MULTIDIODE PL3D™; ContrÂge™, RF ContrÂge™; MULTIDIODE SLP™; VARIUS™; VR1000™, ODONT™

Indication for Use:

The INTERmedic Diode Laser Family (and their delivery accessories used to deliver optical, ultrasound and RF energy) are indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialties including: Urology, Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/Neck/ENT and Radiology, Endovascular coagulation, Oral Surgery and Dental procedures.
Examples include:

- **LASER 810nm and 980nm**

Urology:

- Lesions of external genitalia
- Circumcision
- Condyloma
- Bladder tumors
- Bladder neck incisions
- Vaporization of the prostate

General Surgery

- Rectal an anal hemorrhoidectomy
- Mastectomy
- Dermabrasion
- Appendectomy (open and laparscopic
- Bowel resection (open and laparscopic)
- Colectomy
- Liver resection
- Resections of organs
- Thyriodectomy
- Adhesiolysis
- Hepatobiliary tumors
- Thoracotomy
- Cholecystectomy (open and Laparscopic)
- Condyloma
- Breast biopsy

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)

Over the Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

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

510(k) Number K053540

Statement of Indication for Use

510(k) Number: **K503540**

Neurosurgery:
- Percutaneous Disc Decompression
- Discectomy
- Hemostasis in conjunction with meningiomas

Gynecology:
- Cervical conization
- Myomectomy
- Endometrial ablation
- Ovarian cystectomy
- Appendectomy

Ophthalmology:
- Dacryocystorhinostomy transcanalicular
- Open DCR
- Tumor excision
- Blepharoplasty

Orthopedics:
- Dissect and coagulate

Gastroenterology:
- Hemostasis of colonoscopy
- Hemostasis of esophageal varices
- Excision of polyps

Arthroscopy:
- Chondromalacia
- Synovectomy
- Menisectomy

Thoracic Surgery:
- Thoracotomy
- Pulmonary resection
- Hemostasis
- Pericardiectomy
- Adhesiolysis
- Coagulation of blebs and bullae

Pulmonology:
- Endoscopic pulmonary applications
- Tracheal bronchial lesions
- Benign an malignant pulmonary obstruction

Otolaryngology ENT:
- Removal of benign lesions from the ear, nose and throat
- Excision of carcinoma of the larynx
- Incision and excision of carcinoma in situ
- Neck dissection
- Laryngeal papillomectomy
- Removal of vocal cord/fold nodules, polyps and cysts

Dental applications:
- Frenectomy
- Frenotomy
- Biopsy
- Pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)

Over the Counter Use _____ (21 CFR 801 Subpart C)

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Pulmonary Surgery:

- Endoscopic pulmonary applications
- Tracheal bronchial lesions
- Benign and malignant pulmonary or stricture

Cardiac Surgery:

- Coagulation and hemostasis of cardiac tissue

Dermatology/Aesthetics:

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, veinulectasias of the legs and face
- Treatment of reticular veins and branch varicosities
- Pyogenic granuloma, lymphangioma and lymphagiomatosis disease, angiofibromas.
- Superficial benign vascular lesions including Telangiectasias, Rosacea, Angioma, venous lakes Couperosis, Cherry angioma, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines. Epidermal nevi, spider nevi.
- Dermatological surgery: Condyloma acuminate, warts, small non malignant skin tumors, small semi-malignant tumors as basalomas, Bowe, Kaposi sarcom. Warty leucoplasy and ulcers debridment.
- Seborrheic keratosis
- Mixoid cyst
- Papillary varix
- Acne treatment
- Hair removal of unwanted hair from skin type I-V

Plastic Surgery:

- Cut, coagulation & vaporization
- Resurfacing non
- Blepharoplasty

Vascular Surgery:

- Endoluminal or endovenous laser surgery for saphenous incompetent veins

➢ **ContrÂge RF**

Dermatology/Aesthetics:

- Non invasive treatment of wrinkles and rhytids
- Non invasive scar reduction treatment (acne or traumatic scars)

--- Page 3 of 3 (Total pages Indications for use; 3 pages)

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)

Over the Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K053540

SEP - 6 2006

510(k) Summary
as required by section 807.92(c)
For INTERmedic's Diode Laser Family

K053540

This summary complies with the Federal Performance Standard for Laser Products issued by the Food and Drug Administration (FDA), Center of Devices and Radiological Health (CDRH), in Title 21, Code of Federal Regulations, Subchapter J, Parts 1040.10 and 1040.11.

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Arizona Glass Tech, Inc.
9233 E. Neville Ave. #1128
Mesa, AZ 85212
Phone: 480-241-3795
Fax: 480-445-9903

as United States Agent/Distributor and official correspondent to INTERmedic Arfran, S.A.

See Attachment 1 (United States Agent Notification)

Contact Person: Klaus Sivec

Date of Preparation: November 25th, 2005

Name/Address of Establishment/Owner:

INTERmedic Arfran, S.A.
Avda. Josep Tarradellas, 91
08029 Barcelona
SPAIN

Name of Device: Trade Name: INTERmedic Diode Laser Family 810nm and 980nm (and the delivery accessories that are used with them to deliver Laser Energy), including:

- MULTIDIODE ENDO™ laser 15, 25 and 50
- MULTIDIODE SURGICAL 15™, 30™, 50™, 100™, 120™ & R 15 OFT™
- MULTIDIODE PL3D™
- ContrÂge™, RF ContrÂge™
- MULTIDIODE SLP™
- MULTIDIODE VARIUS™ , VR1000™
- MULTIDIODE ODONT™

Common Name

Medical Laser System (and Accessories)

Classification Name

Laser surgical instrument and accessories for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
Product code: GEX Laser instrument, surgical, powered
Subsequent product code: GEI Electrosurgical, cutting & coagulation & accessories
Panel: 79
Class: II

Predicate Device

PhotoMedex Laser Pro 810, 940 and 980 Diode Laser Systems (K042211, K040294)
Syneron Lasers, Aurora & Polaris (K031993, K050452, K052324, K041969, K041959, K050796)
Ceralas D 980 Diode Laser System (K050824)
Ceralas D 810 Diode Laser System (K032864)
Ceralas G Laser System (K002296)
Dornier's Diode Laser Family (K021724, K000072, K003993, K020339)

Rationale for Substantial Equivalence

The INTERmedic Diode Laser Family including Accessories have the same intended uses and indications for uses as the listed predicate devices, and have similar technological characteristics as the predicate devices – treatment wavelengths, laser media, mode of operation, power output, exposure duration, treatment intervals, laser energy delivery control and therefore is substantially equivalent to the predicate devices.

Device Description

The INTERmedic Diode Laser Family is designed to deliver laser power at wavelengths of 810nm and 980nm, depending on model, that can be used for the procedures indicated in the section "Indication for Use" in this summary. The ContrÂge model can be used with or without the RF unit. The different models can be identified by their different names, output frequency and maximum power.
Each system is comprised with the following main components:

- Operating software controlled by a microprocessor
- A footswitch (detachable)
- A laser cabinet/console with fiber port
- A safety Interlock

Technological Characteristics and Substantial Equivalence

From a clinical point of view and comparing design and specifications, the INTERmedic Diode Laser Family and predicate devices, Ceralas Laser Family from BioLitec, Laser Family from Dornier, Syneron Laser Systems and other listed in predicate devices are substantially equivalent. Based on the overall performance and technological characteristics of the devices, INTERmedic Arfran S.A. believes that no significant differences exist between the INTERmedic Diode Laser Family and the predicate devices. They all work in the same range of wavelength and have the same indications for use.

Indications for use

The INTERmedic Diode Laser Family (and their delivery accessories used to deliver optical, ultrasound and RF energy) are indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialties including: Urology, Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/Neck/ENT and Radiology, Endovascular coagulation, Oral Surgery and Dental procedures. Examples include: (see page 5 in this Summary)

Safety and effectiveness

The INTERmedic Diode Laser Family is designed, manufactured and tested according mandatory and voluntary international Standards. Compared to the previously indicated predicate devices, the introduction of the INTERmedic Diode Laser Family provides no new clinical indications, which have previously demonstrated clinical effectiveness.

Performance Data - Comparison Tables

	INTERmedic ENDO Laser	Dornier K020339 Medilas
Wavelength [nm]	980	940
Peak Power	50W	120W
Pulse Mode	5ms to 10s	10 to 100ms
Laser Medium	Solid-state Diode	Solid-state Diode
Aiming Beam	650nm (red) 5mW max.	Red Standard 0-150µW (adjustable)
Power Requirements	100-120 VAC 50-60Hz 220-240 VAC 50-60Hz	100 – 240 VAC 50-60Hz
Operation Mode	Continuous or pulsed	Continuous or pulsed
Dimensions (HxWxD) [inch]	8x15x19	8x19x20
Weight [lbs]	25	55
Indication for use:	Minimally invasive endovenous treatment of varicose veins (internal and external saphenous and collateral veins) of all diameters under local anesthesia, as well as percutaneous treatments of superficial vascular lesions.	Same

	INTERmedic SURGICAL Laser incl. SR OFT 15	BioLitec K050824 Medilas
Wavelength [nm]	980	980
Peak Power	Up to 120W	100W
Exposure time	5ms to 10s	0.01s to 99.9s
Laser Medium	Solid-state Diode	Solid-state Diode
Aiming Beam	650nm (red) 5mW max.	635nm (red) max. 4mW
Power Requirements	100-120 VAC 50-60Hz 220-240 VAC 50-60Hz	100 – 240 VAC 50-60Hz
Operation Mode	Continuous or pulsed	Continuous or pulsed
Dimensions (HxWxD) [inch]	8x19x19	7x18x15
Weight [lbs]	35	33
Indication for use:	vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialties including: Urology, Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/Neck/ENT and Radiology, Endovascular coagulation, Oral Surgery and Dental procedures.	same

The increase of power to 120W does not affect any safety and security characteristics. The 120W contains additional diodes and has a shorter treatment time on the patient, compare to a 100W or a laser using less wattage..

	INTERmedic PL3D	BioLitec K050824 Ceralas
Wavelength [nm]	980	980
Peak Power	Up to 25W	100W
Exposure time	50ms to cw	0.01-99.9s
Laser Medium	Solid-state Diode	Solid-state Diode
Aiming Beam	650nm (red) 5mW max.	635nm (red) max. 4mW
Power Requirements	100-120 VAC 50-60Hz 220-240 VAC 50-60Hz	100 – 240 VAC 50-60Hz
Operation Mode	Continuous or pulsed	Continuous or pulsed
Dimensions (HxWxD) [inch]	8x19x19	7x18x15
Weight [lbs]	35	33
Indication for use:	Neurosurgery: vaporization, incision, excision, ablation, and coagulation of peripheral soft tissue tumors, discectomy.	Same

	INTERmedic ContrÂge and RF ContrÂge	Syneron K052324, K050452,K0507796 Polaris, Aurora
Wavelength [nm]	980	900-980
Peak Power	Up to 40W	Up to 100W
Exposure time	5ms to cw	n.a.
Laser Medium	Solid-state Diode	Solid-state Diode
Aiming Beam	650nm (red) 5mW max.	n.a.
Power Requirements	100-120 VAC 50-60Hz 220-240 VAC 50-60Hz	Standard 110VAC
Operation Mode	Continuous or pulsed	Continuous or pulsed
Dimensions (HxWxD) [inch]	8x20x16	35.5x15x15
Weight [lbs]	40 + 22 with RF unit	55
RF Frequency	0.45 MHz	n.a.
RF Energy	50 – 150 J/cm^2	Up to 100 J/cm^2
Indication for use:	Aesthtetic, Dermatology for vascular lesions, superficial Benign vascular and pigment lesion treatment, Skin rejuvenation, wrinkle reduction	Same

The ContrÂge laser and RF unit is **not** an anti aging laser.

	INTERmedic SLP	Dornier K050824, K021724, K020339 Medilas D Skin Pulse
Wavelength [nm]	810	940
Peak Power	Up to 90W	120W
Exposure time	5 to 500ms (vascular mode) 50 to 1200ms (hair removal mode)	10 to 100ms
Repetition Rate	1 to 9Hz	Up to 5Hz
Laser Medium	Solid-state Diode	Solid-state Diode
Aiming Beam	650nm (red) 5mW max.	Red aiming beam standard 0-150mW adjustable
Power Requirements	100-120 VAC 50-60Hz 220-240 VAC 50-60Hz	100 – 240 VAC 50-60Hz
Operation Mode	Continuous or pulsed	Continuous or pulsed
Dimensions (HxWxD) [inch]	8x20x18	8x19x20
Weight [lbs]	27	55
Indication for use:	Dermatology, treatment and/or removal of unwanted vascular lesions and removal of unwanted hair, pigment lesions,	Same

	INTERmedic VARIUS and VAIRUS 1000	Dornier K050824, K021724, K020339 Medilas D Skin Pulse
Wavelength [nm]	980	940
Peak Power	Up to 50W	120W
Pulse interval	50 to 900ms	10 to 100ms
Laser Medium	Solid-state Diode	Solid-state Diode
Aiming Beam	635nm (red), 1mW	Red Standard 0-150µW (adjustable)
Power Requirements	100-120 VAC 50-60Hz 220-240 VAC 50-60Hz	100 – 240 VAC 50-60Hz
Operation Mode	Continuous or pulsed	Continuous or pulsed
Dimensions (HxWxD) [inch]	8x15x19	8x19x20
Weight [lbs]	26	55
Indication for use:	Dermatology, Vascular treatment of leg and spider veins, vascular and pigmented lesions and skin treatments and rejuventation cutaneous surgery: cutting, coagulation and vaporization	Same

	INTERmedic ODONT	BioLitec K050824 Ceralas
Wavelength [nm]	800-980	980
Peak Power	Up to 50W	100W
Pulse interval	50 to 900ms	0.01-99.9s
Laser Medium	Solid-state Diode	Solid-state Diode
Aiming Beam	635nm (red), 1mW	635nm (red) max. 4mW
Power Requirements	100-240 VAC 50-60Hz	100 – 240 VAC 50-60Hz
Operation Mode	Continuous or pulsed	Continuous or pulsed
Dimensions (HxWxD) [inch]	7x12x16	7x18x15
Weight [lbs]	18	33
Indication for use:	Oral Surgery, examples include: Root sterilization, hemostasis, biopsy, frenectomy, fibroma removal, abscess incision and draining, pulpotomy,	Same