

DEC 16 1998



K983543

**510 (k) SUMMARY**  
**ACCU-PULSE 1000 CO<sub>2</sub> SURGICAL LASER SYSTEM**

This 510 (k) summary of safety and effectiveness for the *Accu-Pulse 1000* CO<sub>2</sub> Surgical Laser System is submitted in accordance with the requirements set forth in SMDA 1990 and following guidance concerning the organization and content of a 510 (k) summary.

Applicant: Argus Photonics Group, Inc.

Address: 759 Parkway Street, Suite 102  
Jupiter, Florida 33477

Contact Person: Kevin Dickenson, Vice President

Telephone: (561) 748-8151  
(561) 748-8157 (fax)

Preparation Date: 9/30/98

Device Trade Name: *Accu-Pulse 1000* Surgical Laser System

Common Name: CO<sub>2</sub> laser, Pulsed CO<sub>2</sub> Surgical Laser

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (see 21 CFR 878.4810)

Legally Marketed Predicate Device: *Accu-Pulse* pulsed CO<sub>2</sub> laser manufactured by Argus Photonics Group, Inc.

Description of the *Accu-Pulse 1000* CO<sub>2</sub> Laser: *Accu-Pulse 1000* is a DC excited gas-slab pulsed CO<sub>2</sub> laser which produces 1-15 watts average power (see below for additional Surgical specifications).

Intended Use of the *Accu-Pulse 1000* CO<sub>2</sub> laser: The intended use is the same or similar to that of the *Accu-Pulse* pulsed CO<sub>2</sub> laser marketed by Argus Photonics, Inc., i.e:  
"For use in cutting, vaporizing and coagulating soft tissue for clinical applications in dermatology, plastic surgery, podiatry, neurosurgery, gynecology, otorhinolaryngology, arthroscopy, open & endoscopic general surgery".

**Table of Substantial Equivalence**

<b>FEATURE</b>	<b>Tissue Technologies <i>Tru-Pulse</i></b>	<b>Argus Photonics <i>Accu-Pulse</i></b>	<b>Argus Photonics <i>Accu-Pulse 1000</i></b>
Power	1- 10 Watts	1-15 Watts	1-15 Watts
Wavelength	10.6 microns	10.6 microns	9.6 or 10.6 microns
Indications for Use	Coagulation, vaporization, ablation of or cutting of soft tissue in dermatology, plastic surgery, podiatry and otorhinolaryngology	Coagulation, vaporization, ablation of or cutting of soft tissue in dermatology, plastic surgery, podiatry and otorhinolaryngology	Coagulation, vaporization, ablation of or cutting of soft tissue in dermatology, plastic surgery, podiatry and otorhinolaryngology
Laser Type	DC slab excited	DC slab excited	DC slab excited
Spot Size	1,3, 5mm	3mm, 5mm & 7mm	250 microns-3mm
Average Power	1-10 Watts	1-15 Watts	1-15 Watts
Mode	Multi-mode	Multi-mode	TEM 00
Exposure Duration	< 250 $\mu$ s	4 $\mu$ s	4-10 $\mu$ s
Control System	Microprocessor, self diagnosis	Microprocessor, self diagnosis	Microprocessor, self diagnosis
Repetition Rate	1-20 Hz	0.5-5Hz	1-20 Hz
Aiming Beam	633 nanometer	633 nanometer	633 nanometer
Excitation	DC excited	DC excited	DC excited

- Performance Data: None. The specifications and intended use of the *Accu-Pulse 1000* Surgical Laser System are the same or very similar to those of the *Accu-Pulse* pulsed CO<sub>2</sub> laser. Because of this, performance data were not required.
- Software Validation: Argus Photonics Group, Inc., has implemented a Software Development Procedure outlined in the following pages. This software will be verified and validated by programmers as each element is added to the program. In addition, the software will be challenged by intentional breaches or breaks in interlocks and / or input parameters. Argus Photonics Group certifies that software validation will occur prior to the sale of the *Accu-Pulse 1000* laser system described herein.
- Conclusion: Based on the foregoing, Argus Photonics Group, Inc., believes that the *Accu-Pulse 1000* CO<sub>2</sub> Surgical Laser System is substantially equivalent to a legally marketed predicate device, i.e. the *Accu-Pulse* Pulsed Surgical Laser as marketed by Argus Photonics Group, Inc., (K971830).



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Kevin Dickenson  
Vice President  
Argus Photonics Group, Incorporated  
759 Parkway Street, Suite 102  
Jupiter, Florida 33477

Re: K983543  
Trade Name: Accu-Pulse 1000 Surgical Laser System  
Regulatory Class: II  
Product Code: GEX  
Dated: September 30, 1998  
Received: October 9, 1998

Dear Mr. Dickenson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

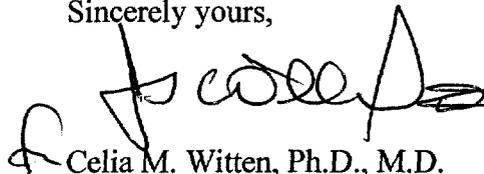
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

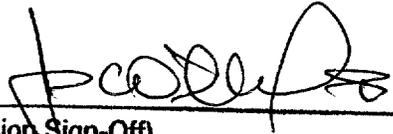
Enclosure

K983543

### INDICATIONS FOR USE

For use in cutting, vaporizing and coagulating soft tissue for clinical applications in dermatology, plastic surgery, podiatry, neurosurgery, gynecology, otorhinolaryngology, arthroscopy, open & endoscopic general surgery.

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices

510(k) Number 12983543