



K97 1830

AUG 14 1997

510 (k) SUMMARY
ACCU-PULSE CO₂ SURGICAL LASER SYSTEM

This 510 (k) summary of safety and effectiveness for the *Accu-Pulse* CO₂ 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: 5/14/97

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

Common Name: CO₂ laser, Pulsed CO₂ 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: *Tru-Pulse*TM pulsed CO₂ laser manufactured by Tissue Technologies, Inc.

Description of the *Accu-Pulse* CO₂ Laser: *Accu-Pulse* is a DC excited gas-slab pulsed CO₂ laser which produces 1-15 watts average power (see below for additional Surgical specifications).

Intended Use of the *Accu-Pulse* CO₂ laser: The intended use is the same or similar to that of the *Tru-Pulse* pulsed CO₂ laser marketed by Tissue Technologies, 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

FEATURE	Coherent <i>UltraPulse</i>	Tissue Technologies <i>Tru-Pulse</i>	Argus Photonics <i>Accu-Pulse</i>
Power	2- 120 Watts	1- 10 Watts	1-15 Watts
Wavelength	10.6 microns	10.6 microns	10.6 microns
Energy Density at Tissue	5J/cm ²	5J/cm ²	5J/cm ²
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	RF slab excited	DC slab excited	DC slab excited
Spot Size	3mm-2 cm	1,3, 5mm	3mm, 5mm & 7mm
Average Power	1-100 Watts	1-10 Watts	1-15 Watts
Mode	TEM 00	Multi-mode	Multi-mode
Exposure Duration	< 950 μs	< 250 μs	<250 μs
Control System	Microprocessor, self diagnosis	Microprocessor, self diagnosis	Microprocessor, self diagnosis
Repetition Rate	1Hz- continuous	1-20 Hz	1-5 Hz
Aiming Beam	633 nanometer	633 nanometer	633 nanometer
Excitation	RF excited	DC excited	DC excited

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- Performance Data: None. The specifications and intended use of the *Accu-Pulse* Surgical Laser System are the same or very similar to those of the *Tru-Pulse*TM pulsed CO₂ 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* laser system described herein.
- Conclusion: Based on the foregoing, Argus Photonics Group, Inc., believes that the *Accu-Pulse* CO₂ Surgical Laser System is substantially equivalent to a legally marketed predicate device, i.e. the *Tru-Pulse*TM Pulsed Surgical Laser as marketed by Tissue Technologies, Inc., (K952049).
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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

AUG 14 1997

Re: K971830
Trade Name: Accu-Pulse Carbon Dioxide Laser System
Regulatory Class: II
Product Code: GEX
Dated: May 14, 1997
Received: May 16, 1997

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.

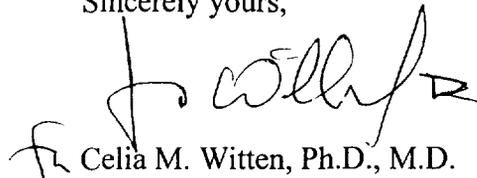
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, 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.

Page 2 - Mr. Kevin Dickenson

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". The signature is stylized and includes a small 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

K971830

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)

[Handwritten mark]

[Handwritten signature]

(Division Sign-Off)
Division of General Restorative
510(k) Number _____

K971830