K970804

Attachment I
510(K) Summary
Tru-Pulse CO2 Surgical Laser System

JUN - 3 1997

This 510(K) Summary of safety and effectiveness for the Tissue Technologies, Inc. Tru-Pulse™ CO2 Surgical Laser system is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant: Address:	Tissue Technologies, Inc. 4432 Anaheim NE Albuquerque, NM 87113
Contact Person:	Sandra Hansen, Regulatory Affairs
Telephone:	(505) 828-0508 (505) 828-0525
Preparation Date:	3-1-97
Device Trade Name:	Tru-Pulse™ CO2 Surgical Laser
Common Name:	CO2 Surgical Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX 21 CFR 878-48
Legally Marketed Predicate Device:	UltraPulse® Pulsed CO_2 Laser manufactured by Coherent
Description of the Tru-Pulse™ CO2 Surgical Laser	Tru-Pulse™ Pulsed CO2 Surgical laser is an Rf excited gas-slab pulsed CO2 laser which produces 1-10 watts average power
Intended use of the Tru-Pulse™ CO2 Surgical Laser	This intended use is the same or similar to that for the UltraPulse® Pulsed CO_2 Laser manufactured by Coherent, i.e. "clinical applications in dermatology, plastic surgery, podiatry, neurosurgery, gynecology, otorhinolaryngology, arthroscopy, open and endoscopic general surgery.
Nonclinical Performance Data: Clinical Performance Data:	None None
Conclusion:	The intended us is the same or similar to that for the UltraPulse Pulsed CO2 laser marketed by Coherent, i.e.: Clinical applications in dermatology, plastic surgery., podiatry,. neurosurgery, gynecology, otorhinolaryngology, arthroscopy, open and endoscopic general surgery.
Additional Information:	None requested at this time

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 1997

Ms. Sandra Hansen
Regulatory Affairs
Tissue Technologies, Inc.
4432 Anaheim NE
Albuquerque, New Mexico 87113

Re: K970804
Trade Name: Tru-Pulse™ CO2 Surgical Laser
Regulatory Class: II
Product Code: GEX
Dated: March 1, 1997
Received: March 4, 1997

Dear Ms. Hansen:

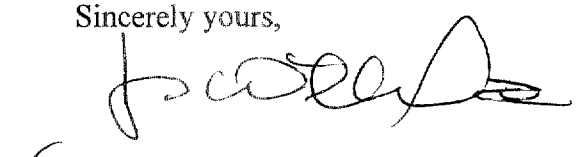
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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,



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

INDICATION FOR USE STATEMENT

510(k) Number: K970804

Device Name: Tru-Pulse™ CO2 Surgical Laser

Indications for Use:

Coagulation, vaporization, ablation, or cutting of soft tissue in dermatology and plastic surgery, general surgery, podiatry and otorhinolaryngology.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970804

Prescription Use X OR Over-the-Counter Use____
(per 21 CFR 801.109)