DEC 1 1 2001

510 (K) SUMMARY

Manufacturer:	VidaMed, Inc. 46107 Landing Parkway Fremont, CA 94538 510-492-4900 510-492-4999 (fax)
Contact	Dr. Yi Chen, RAC
Date of Preparation	November 30, 2001
Trade Name	Precision™ TUNA® Office System PROVu™ TUNA® System
Common Name	Electrosurgical Generator and Accessories
Classification Name	Electrosurgical Cutting and Coagulation Devices and Accessories
Substantial Equivalence	The same products listed above
Product Code	GEI KNS
21 CFR Section	878.4400 876.4300
Device Description	Each System of the TUNA System Product Family consists of a RF Generator, a sterile single-use Cartridge attached to a reusable Handle, a reusable Telescope, a single-use Return Electrode, a sterile single-use Tubing set, and other accessories.
Indication for Use	Each System of the TUNA System Product Family is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cc.
Technology Characteristics	Each System of the TUNA System Product Family delivers low levels of 460 kHz RF energy up to 15 W from each of the 2 needles directly into prostatic tissue to produce a localized necrotic lesion to treat the symptoms associate with BPH.
Test Summary	In two multi-centers clinical studies a total of 50 patients with both lateral and median lobe enlargement were treated with the VidaMed Tuna System to relieve their symptoms of BPH and improve their uroflow. The studies demonstrated safety and efficacy in using the VidaMed TUNA system. It was further demonstrated that a shortened needle length across the median lobe starting 1 cm down from the bladder neck and penetrating directly into the adenoma and applying RF energy has not increased the risks associated with the use of the TUNA system from that of treating the lateral lobes. Therefore, it was concluded that the contraindication of patient's with an enlarged middle lobe can be deleted.

Clinical Study Design
Clinical studies using the TUNA® procedure were performed at multiple medical institutions throughout the United States. Patients with lower urinary tract symptoms secondary to benign prostate hyperplasia (BPH) were enrolled in separate clinical studies to determine the safety and efficacy of TUNA®.

An arm of this clinical study included a multicenter, single blind, randomized study comparing TUNA® to TURP. Of the 167 patients treated in the study, 111 were treated with TUNA® and 56 were treated with TURP. Safety was measured by the rate and severity of adverse events. Efficacy was evaluated by measuring peak flow rate and AUA symptom score.

Patients 45 years or older with lower urinary tract symptoms secondary to the diagnosis of BPH who have both lateral and median lobe involvement were enrolled in additional 2 studies (PM1 and P01) to determine safety and efficacy. The prostate glands were between 30 to 100 grams. Of the 50 patients treated in the studies, 45 were followed up for 6 months and 24 had up to 1 year follow-up data.

Safety Data
The clinical trials demonstrated that the TUNA® procedure can be performed without the need for general or regional (spinal) anesthesia; however, sedation is often used. Treatment with TUNA® procedure is associated with few side effects and adverse events. The following table summaries the safety data of patients from the original TUNA® vs. TURP study (lateral lobe only) and that from the 2 additional studies (P01 and PM1) that included treatment of patients having a degree of median lobe hyperplasia.

Table 1-1 Adverse Events

Adverse Event	Original TUNA® Lateral Lobe Studies	P01 Lateral and Median Lobe Studies	PM1 Lateral and Median Lobe Studies
Obstruction	44%	0%	0%
Catheterization (for urinary retention)	41%	15%	6%
Bleeding	29%	9%	6%
Pain/Discomfort	23%	* (included in Dysuria)	* (included in Dysuria)
Urgency	8%	* (included in Dysuria)	* (included in Dysuria)
Frequency	8%	* (included in Dysuria)	* (included in Dysuria)
Urinary Tract Infection	6%	12%	0%
Dysuria	2%	15%*(irritative symptoms)	6%*(irritative symptoms)
Scarring/Stricture	<2%	0%	0%
Impotence	<2%	0%	0%
Retrograde Ejaculation	<1%	3% (partial)	0%
Incontinence	0%	0%	0%

* In the lateral & median lobe studies, Dysuria was described as irritative voiding symptoms, which include pain, discomfort urgency, or frequency.

Efficacy Data
The original prospective clinical trial (lateral lobe only) was performed at eight (8) medical centers across the United States. One hundred and sixty seven (167) men over 50 years of age or older with symptomatic BPH were enrolled in this original trial. One hundred and twenty one (121) of these patients were randomized to either TUNA® or TURP: sixty five (65) were treated with TUNA® and fifty six (56) underwent TURP. Forty six (46) additional non-randomized patients were treated with TUNA, making the total TUNA® treated population one hundred and eleven (111).

Mean change and percentage change from baseline and between the two groups for AUA (American Urological Association) symptom score, quality of life (QOL) score and post void residual urine volume were measured at 12 months following treatment.

Table 1-2 Efficacy Data of the TUNA* vs. TURP Study

Parameter	Timepoint		
	Baseline	6 month	12 month
AUA Symptom Score			
TUNA	23.8	10.6	11.9
TURP	24.1	7.9	7.8
Peak Flow Rate			
TUNA	8.9	13.4	14.8
TURP	8.9	21.0	21.1
Post Void Residual Volume			
TUNA	91.4	63.6	65.9
TURP	81.9	45.6	47.1
Quality of Life			
TUNA	4.7	1.9	1.9
TURP	4.8	1.6	1.4

* TUNA treated 111 patients

Similar results were seen from the additional studies (lateral and median lobes). Tables 1-3 and 1-4 demonstrated the efficacy results of the all studies.

Table 1-3 Total Symptom Score Overview

Visit	Original TUNA Lateral Lobe Studies (American Urological Association Symptom Score)	P01 Lateral and Median Lobe Studies (International Prostate Symptom Score)	PM1 Lateral and Median Lobe Studies (International Prostate Symptom Score)
Pretreatment	24.6	21.0	24.0
1 Month	12.5	16.0	13.0
3 Month	9.6	10.0	10.0
6 Month	10.1	10.0	5.0
12 Month	10.6	11.0	N/A

Table 1-4 Peak Uroflow Rate (Qmax) Overview

Visit	Original TUNA Lateral Lobe Studies	P01 Lateral and Median Lobe Studies	PM1 Lateral and Median Lobe Studies
Pretreatment	8.306	8.6	6.4
1 Month	16.565	10.2	11.4
3 Month	15.024	12.0	15.1
6 Month	14.748	13.7	11.0
12 Month	13.432	12.7	N/A

As of 2000, over 25,000 patients worldwide have been treated with TUNA®, with over 6,000 in the United States. TUNA® has proved to be a successful minimally invasive therapy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1 2001

Dr. Yi Chen, R.A.C.
Director of Regulatory Affairs
and Quality Assurance
VIDAMED®
46107 Landing Pkwy
FREMONT CA 94538

Re: K012587
Trade/Device Name: As identified in Enclosure 1
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: 78 KNS
Regulation Number: 21 CFR §878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: 79 GEI
Dated: September 27, 2001
Received: September 28, 2001

Dear Dr. Chen:

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); 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.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures
(1) Trade/Device Name
(2) Indications for Use

INDICATIONS FOR USE

Page _____ of _____

510 (k) Number (if known): K012587

Device Name: TUNA® System Product Family, including Precision™ TUNA® Office System PROVu™ TUNA® System

Indications For Use:

The TUNA® System Product Family, including Precision™ TUNA® Office System and PROVu™ TUNA® System, is indicated for use in the treatment of symptoms due to urinary outflow obstruction secondary to Benign Prostatic Hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cc.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012587

(Optional Format 1-2-96)