AUG 26 1999

K991847
PG. 1 OF 4

Argomed, Inc.'s Thermoflex system

Name of Device	Thermoflex™ Water-Induced Thermotherapy (WIT) System
Common or Usual Name	Thermal Therapy BPH Catheter System or WIT System
Classification Names	Electrosurgical Cutting and Coagulation Device (21 C.F.R. § 878.4400), Laser Surgical Instruments (21 C.F.R. § 878.4810), and Urethral Dilator (21 C.F.R. § 876.5520)
Product Codes	GEI, GEX, and KOE
Submitter	Argomed, Inc. 3800 Gateway Centre Boulevard Suite 308 Morrisville, North Carolina 27560
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Contact Person:	Richard B. Klein
Date Prepared:	May 28, 1999

Predicate Devices

Trade Name	Manufacturer	510(k)
Transurethral Needle Ablation ("TUNA") System	VidaMed, Inc.	K965199, K960918, and K951245
Optilase® Nd:YAG Laser ("VLAP") system	Trimedyne, Inc.	K954597
Prostatic Balloon Dilation Catheter	Apex	K913477

Intended Use

The Thermoflex system, the VidaMed TUNA system, and the Trimedyne VLAP system have the same intended use: to provide thermal treatment to the prostate to treat symptoms due to urinary outflow obstruction secondary to BPH. The Thermoflex system and the Apex catheter are intended to treat symptoms due to urinary outflow obstruction secondary to BPH. The Thermoflex system and the predicate devices are indicated for use in men over the

age of 50 years exhibiting the symptoms of urinary outflow obstruction. Both the Thermoflex system and the VidaMed TUNA system define limits on the length or size of the prostate prior to treatment to insure that thermal treatment is provided to the target tissue without exposure of non-target tissue. For the Thermoflex system, the minimum prostate length, to be determined by cystoscopic examination, is 2.0 cm, and the maximum length is 6.4 cm. For the VidaMed TUNA system, the prostate must be between 20 cc and 50 cc in size. Thus, the Thermoflex system has the same intended use and similar indications for use as these predicate devices.

Substantial Equivalence

The Thermoflex system, the VidaMed TUNA system, the Trimedyne VLAP system, and the Apex Prostatic Catheter have the same intended use: the treatment of symptoms due to urinary outflow obstruction secondary to BPH. The Thermoflex system and the predicate devices have similar principles of operation and technological characteristics. Each device is inserted into the urethra and serves to relieve pressure placed on the urethra by the prostate. Relief of the pressure reduces the symptoms of urinary outflow obstruction. As opposed to surgical procedures, such as transurethral resectioning of the prostate ("TURP"), the Thermoflex system and the TUNA and VLAP predicate devices displace and necrose prostatic tissue by the application of heat to the prostatic tissue. The Thermoflex system and the Apex Prostatic Catheter both relieve pressure of the prostate on the urethra by the application of pressure induced by dilation of the catheter.

The technological differences between the Thermoflex system and its predicate devices are the combination of heat transfer with dilation, the method of heat generation, the control of the generated heat, and the point of energy delivery within the prostate.

The Thermoflex system combines pressure from dilation of the catheter with the introduction of heat into the prostatic tissue to induce coagulation necrosis. The pressure from the Thermoflex system dilation balloon allows the uniform distribution of heat to the prostate providing the therapeutic necrotic effect. With the Thermoflex system, heat is generated externally to the body, and then circulated to the prostate through an insulated catheter that protects non-target tissues, such as the rectum, the bladder, and the penile urethra. The VidaMed TUNA and the Trimedyne VLAP systems generate heat within the prostate by the conversion of RF energy or radiant light into heat. Heat is controlled in the Thermoflex system by the lack of energy generation within the prostate. The heated water cannot increase in temperature or impart additional energy into the prostate, as no energy source is present within the body. Both the Thermoflex system and the Trimedyne VLAP system apply the heat directly to the prostatic urethral lumen, inducing coagulation necrosis. The VidaMed TUNA

system employs RF probes that are inserted through the urethral lumen into the prostate itself.

Performance Characteristics

The Thermoflex system is a catheter based thermal therapy device for the treatment of symptoms due to urinary outflow obstruction secondary to BPH. The Thermoflex system combines a heating console/pump with a sterile, multiple balloon WIT prostatic catheter. Following insertion of the WIT prostatic catheter into the bladder through the urethra, a "locating" balloon is filled with a small volume of air and positioned within the bladder neck to insure proper placement of the treatment balloon within the prostate. A predetermined volume of water is added to the balloon dilation catheter ("treatment balloon"), causeing the treatment balloon to dilate within the prostate, creating pressure and insuring contact of the treatment balloon's surface with the prostatic tissue. Water is heated externally to the body and pumped through the thermally insulated catheter to the treatment site and back to the heating console/pump. At the treatment site, heat from the water is exposed to the urethra and prostatic tissue by means of physical contact of the treatment balloon with the target tissue. Heat from the water is transferred conductively to the tissue, inducing tissue ablation due to coagulation necrosis and tissue devitalization.

The equivalence of the Thermoflex system to the predicate devices in the treatment of symptoms of urinary outflow obstruction secondary to BPH was assessed in a multicenter, nonrandomized, prospective clinical study of a single patient group. The objectives, study endpoints, and methods of analysis focused upon assessing changes in severity of BPH symptoms and signs from pretreatment to post-treatment, and in a comparison of these endpoints to published safety and effectiveness information available for the TUNA system and VLAP system predicate devices. The clinical evaluation demonstrated that the Thermoflex system for Water-Induced Thermotherapy treatment of BPH induced clinically and statistically significant improvements in urine flow rates, prostate volume, prostate symptomatology, and quality of life assessments. The adverse events observed using this device are typical for devices used to treat BPH or for catheterization in general. Thus, the WIT procedure using the Thermoflex system is a safe and effective treatment for BPH..

Conclusion

The Thermoflex system has the same intended use and very similar principles of operation, technological characteristics, clinical efficacy, and clinical safety as a combination of several class II predicate devices, the VidaMed, Inc. Transurethral Needle Ablation ("TUNA") system (K965199, K960918, and K951245), the Trimedyne Optilase® Nd:YAG Laser ("VLAP") system (K954597), and the Apex Prostatic Balloon Dilatation Catheter (K913477). Thus, the

Thermoflex system is substantially equivalent to legally marketed devices intended to treat symptoms due to urinary outflow obstruction secondary to BPH.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 1999

Mr. Richard B. Klein
President & CEO
ARGOMED, Inc.
3800 Gateway Centre Blvd.
Suite 308
Morrisville, NC 27560

Re: K991847
Thermoflex™ Water-Induced
Thermotherapy System
Dated: May 28, 1999
Received: May 28, 1999
Regulatory Class: II
21 CFR §876.4300/Procode: 78 KNS
21 CFR §876.5520/Procode: 78 KOE
21 CFR §878.4810/Procode: 79 GEX

Dear Mr. Klein:

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 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). 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.

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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991847

Device Name: Argomed, Inc. Thermoflex™ Water-Induced Thermotherapy System

Indications for Use:

The Thermoflex system is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia ("BPH"). It is indicated for use in men over the age of 50 years with prostate lengths between 2.0 cm and 6.4 cm who present symptoms of urinary outflow obstruction secondary to BPH.

(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 Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991847

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)