

K980997

SEP 28 1998

510K SUMMARY

A. DEVICE NAME

1. Trade and Proprietary Name: PGK Device (modified)
2. Common Name: PGK Device
3. Classification Name: PGK Device (modified), Class II

B. SUBMITTER'S NAME

1. Address:
PGK Enterprises, Inc.
1201 Ballantrae Lane
McLean, Virginia 22101
2. Phone Number:
703-356-9674 (tel), 703-356-9589 (fax)
3. Contact Person:
Panos Koutrouvelis, M.D.
4. Summary Preparation Date:
March 13, 1998

C. DEVICE DESCRIPTION

1. Function & Scientific Basis: The function and scientific basis of the modified PGK device are similar to that of the predicate PGK device (K911974) in that both ~~are used~~ in conjunction with computerized tomography (CT) to guide needles into an accurate position in the human body for diagnostic and therapeutic purposes. The modified device is used for the accurate placement of needles and delivery of radioactive sources to the correct position in the diseased prostate. See Panos G. Koutrouvelis' article entitled Three-Dimensional Stereotactic Posterior Ischiorectal Space Computerized Tomography Guided Brachytherapy of Prostate Cancer: A Preliminary Report as published in the *Journal of Urology* in tab 4 as well as the unpublished booklet produced by the Uro-Radiology Prostate Institute ("URPI booklet") in tab 5.

2. Physical/Performance Characteristics: Like the predicate PGK device, the modified PGK device includes a stereotactic bridge made of stainless steel and an aluminum protractor, which is attached to the bridge. (See figure 1 in *Journal of Urology* article in tab 4 and drawings in tab 3.) The template (tab 3) in the modified PGK device, which substitutes the guidance device in the predicate PGK, is made of teflon. A post and bracket attachment to the template is made of stainless steel. The modified PGK is manufactured by Associated Design and Manufacturing (Registration #1122860) at 814 N. Henry St., Alexandria, Virginia.

D. INTENDED USE STATEMENT

The PGK device (modified) is used for brachytherapy in the treatment of known or suspected disease of the prostate.

E. PREDICATE DEVICE

The modified PGK device is substantially equivalent to the following legally marketed devices ("Predicate Device"):

1. Device Name: PGK Stereotactic Device
Manufacturer: Associated Design & Manufacturing
510K Number: K911974
Substantial Equivalence Date: 10/28/91
2. Device Name: B & K Stepper, B & K Stepper Matrix
Manufacturer: Brnel & Kjaer Medical
510K Number: K905198, K914945
Substantial Equivalence Date: 8/28/91 & 6/26/92

F. COMPARISON WITH PREDICATE DEVICES

1. PGK Stereotactic Device (K # 911974)

The PGK predicate device and the modified PGK device are similar in the following respects: the stainless steel stereotactic bridge mounted on the CT table above the patient and the aluminum protractor connected to the bridge (Fig. 1 in tab 4 and Fig. 2 in tab 3).

In addition, the free motion of the patient in and out of the gantry with feet first is common to the use of both devices.

Summary of Modifications: The guidance device (Fig. 7 in tab 9) used as a needle holder for needle insertion has been replaced by the template that is mounted on the 3D system and placed above the ischiorectal area. (See Fig. 1 in tab 4 and drawings in tab 3). The template has a surface area of 80 x 130 mm and a thickness of 25 mm. An area of 70 x 80 mm of the template is precision bored to accept 18 gauge needles in both directions. The template is made of Teflon R (DuPont Corp.). The perforations serve to guide the needles, and the 2.5 mm spacing is selected to allow for correction of needle placement as may be required. The template includes 16 holes per square cm.

At its proximal end, the template is affixed by a stainless steel T-shaped connector (see adaptor locating block in drawing in tab 3) to the arm of the stereotactic system, thus allowing the template to rotate in place as needed.

At its distal end, the template has a proper size hole to which a stainless steel post that is graduated at a spacing of 5mm can be attached (see tab 3). The post slides along the hole in the template and its position can be fixed with a locking nut. Attached to the post is a needle holding bracket that slides up and down the post and pivots horizontally in such a way as to allow needle alignment to a specified hole of the template. The bracket can be securely fastened on the post via a knob. This post and bracket attachment is used for implant of radioactive seeds in strand (see Figures 3a-c in tab 3.)

Use of Radioactive Seeds: The modified PGK device is used for delivery of Iodine¹²⁵ or Palladium¹⁰³ seeds that are purchased from Amersham or Theragenics (tab 6). Loose seeds are placed at the correct position with the use of a Mick applicator (K# 890341), the same applicator used by ultrasound guided techniques (see brochure in tab 6). For seeds in strand, each strand contains 10 seeds in line spaced 10 mm apart in special suture that can be cut at any length containing 2-6 seeds (see tab 6). Placement of the seeds in strand is accomplished with the assistance of the post and bracket attachment as

described above. The post and bracket attachment is designed to stabilize the insertion of the needles, avoiding human error during extraction of the afterloading needles.

Sterilization: Materials used during brachytherapy are sterilized in the following ways: (1) needles and the iodine seeds in strand are delivered sterilized to the facility in sterilized containers (2) the template, the post and bracket attachment, the Mick applicator, and all surgical equipment are sterilized in glutaraldehyde 3.4% and inert ingredients 96.6% (Cidex), and (3) loose seeds of palladium and iodine, the seed assembly, and bowls are temperature sterilized at the facility. The template and the needles are the only materials that come into physical contact with the patient except, of course, the radioactive seeds. The template and the needles are similar to those used with predicate device #2.

Radiation Safety Considerations: The safety considerations for handling the radioactive seeds are the same as that in the predicate #2 and are governed by the appropriate license issued by the Nuclear Regulatory Commission, a copy of which can be found in tab 7. Further to safety considerations, pre- and post- implant QA, implant control and summary, and other forms related to radiation survey of the premises are completed for each procedure (*see* copies of forms in tab 7).

Dosimetry: Dosimetry is accomplished in two phases on a special computer program (tab 6) First, the position of the seeds in a rectangular 3-D array, 1 cm apart in each of the three coordinate directions, results on average in a peripheral dose of 16,000 cGy for Iodine¹²⁵ and 12,000 cGy for palladium¹⁰³. To finalize the treatment plan, adjustments in position is made to compensate for prostate movement during the procedure and accurate accounting of seeds (*see* tab 6). Second, three dimensional isodose curves are determined with reference to the final treatment plan and the special computer program. A series of two-dimensional isodose curves in each coordinate direction is calculated (*see* tab 6). Five mm CT images are taken for final verification of implanted radioactive sources (*see* tab 8).

2. Ultrasound-Guided Transperineal Device (Stepper Unit, Stepper Matrix K905198, K914945)

Predicate device K#905198, 914945 is used for radioactive seed implant in patients with prostate cancer. A complete description of the device can be found in the manufacturer's brochure (Tab 10) and in an article published by Drs. Grimm, Blasko and Ragde in the *Atlas of the Urologic Clinics of North America* (tab 11). This article includes a diagram of the technique represented in figure 1, a pubic arch study in figure 4, dosimetry considerations in figures 6 and 7, the stabilizing apparatus in figure 9, and verification in figures 10-11. Additional reading on ultrasound-guided brachytherapy can be found in an article by Russell and Blasko in *Problems in Urology* in tab 11.

The stepping unit in the B & K system is analogous to the stereotactic bridge in the PGK device (modified and predicate). Both the B & K system and the modified PGK device use a template for needle insertion. B & K's stepper matrix (K# 905198, K914945), which represents B & K's template for needle insertion, can be found in the B & K brochure (tab 10) and the Grimm, Blasko and Ragde article (tab 11). The modified PGK device template is similar to the B & K stepper matrix.

Comparison of Similarities and/or Differences. The modified PGK device and the B & K predicate device are used for radioactive seed implant to treat prostate cancer. The implant procedure that uses the modified PGK device differs from that which uses the B & K system in that the former uses CT and a transischioirectal approach rather than ultrasound guidance and a transperineal approach. As such, there are several advantages to 3-D stereotactic CT-Guided transischioirectal brachytherapy over the transperineal approach with transrectal ultrasound guidance:

- Pubic arch interference significantly impedes needle insertion under the transperineal approach. (See p.115 of Grimm, Blasko and Ragde article in tab 11). This obstacle is completely eliminated with the transischioirectal space approach. (See Journal of Urology article in tab 4).
- The transrectal ultrasound guided technique is usually not recommended for patients with large prostates over 60 cm³. The transischioirectal space approach with CT guidance and the PGK 3-D stereotaxis can be used on patients with prostatic volumes

of up to 150 cm³. (See abstract submitted by PG Koutrouvelis, et al. to the American Brachytherapy Society in tab 4.) (See also patient profile charts on p. 8 in URPI booklet in tab 5.)

- Verification and correction, if needed, of needle position during the procedure is possible under the transischiorectal space approach with the PGK designed template. This is more difficult with transperineal approach under ultrasound guidance. (See Journal of Urology article in tab 4 and figures on p.6 of URPI booklet in tab 5)
- The transperineal method is usually not recommended for patients with TURP defects because of risk of developing incontinence. (See p. 471 of Vijvberg article and p.115 of Grimm, Blasko and Ragde article in tab 11). In over 200 patients, including 30 with TURP defects, treated with the transischiorectal space approach, none developed complications of incontinence. (See URPI booklet in tab 5.) With the transischiorectal space approach, the risk is avoided as seeds are not placed in the wall of the urethra.
- Obstructive urinary symptoms are not contraindicated with the transischiorectal space approach as it usually is with transperineal approach with ultrasound guidance. Patients with such symptoms have been treated successfully with the transischiorectal approach.
- With the transischiorectal space approach, the prostate is separated from the rectum by approximately 1 cm. This is accomplished by the forward motion of the prostate during the dorsal approach of needle insertion. As a result, the likelihood of seeds being implanted in the rectal wall is minimized.

Complications: Patients treated with the transischiorectal CT-guided approach may experience treatment-related symptoms such as transient diarrhea, constipation, frequency of urination and/or burning sensation during urination, all of which usually subside in 1-3 months after the procedure. In the case of iodine¹²⁵ implants, the peak of discomfort occurs at some point 4-8 weeks after the procedure, while that for palladium¹⁰³ occurs 2 weeks after. However in some patients the symptoms may persist for a longer duration. Approximately 2% of patients have complained of burning during ejaculation. In addition, patients may experience weak stream during urination; however, no patient thus far has had urethral stenosis requiring TURP. Approximately 4% of patients have required a catheter for 1-2 weeks after the implant to relieve acute obstructive symptoms. See Table 1 for comparison of morbidity and complications associated with the transperineal alone vs. transischiorectal approaches.

Table 1. Morbidity and Complications Comparison

	Ischiorectal Space Approach*	Transperineal Approach [#]
Number of Patients	130	196
Time Period	6-24 months	13-64 months
Gleason's Range	2-9	2-7
PSA (ng/ml)		
Initial	median, 13; range, .9-143ng/ml	--
Post	<2 in 95%	--
Prostate Volume	range, 30-156 cc.	< 60 [†]
Operative Complications	none	negligible
< 12 month		
retention/hematuria	4	14
irritative uropathy	4	19
> 12 month		
chronic uropathy	2	14
urethral necrosis	0	6
incontinence	0	11
chronic infection	2	2
recurrent hematuria	2	2
stricture	0	3
late proctitis	2	2
fistula	0	0
enteritis	0	0

* See Three-Dimensional Stereotactic Posterior Ischiorectal Space Computerized Tomography Guided Brachytherapy of Prostate Cancer: A Preliminary Report. PG. Koutrouvelis. *Journal of Urology*. 159:142-145, 1998 in tab 4 and URPI booklet in tab 5. [#]See Transperineal Ultrasound-Guided Implantation of the Prostate: Morbidity and Complications. JC Blasko, H Ragde, and PD Grimm. *Scand J Urol Nephrol Suppl*. 137: 113-118, 1991 in tab 12. [†]See patient selection criteria in Ultrasound-Guided Transperineal Implantation of Iodine¹²⁵ and Palladium¹⁰³ for the Treatment of Prostate Cancer. PD Grimm, JC Blasko, and H Ragde, *Atlas of Urologic Clinics of North America*. 2:113-125, 1994 in tab 11.

G. PROPOSED LABELING

The modified PGK device with CT guidance and the transischioirectal approach can be used for accurate seed placement to the diseased prostate away from the vital areas such as the urethra and rectum. The procedure itself is fast, convenient, and CT-verified. The size of the prostate, the presence of TURP defects, obstructive uropathy, and pubic arch do not limit the application of the procedure.



Food and Drug Administration
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SEP 28 1998

Panos G. Koutrouvelis, Ph.D.
Medical Advisor
PGK Enterprises, Inc.
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Vienna, Virginia 22182

Re: K980997
Modified PGK Device
Dated: July 14, 1998
Received: July 14, 1998
Regulatory class: II
21 CFR 892.5050/Procode: 90 IWJ

Dear Dr. Koutrouvelis:

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.

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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page _____ of _____

510(k) Number (if known): K980997

Device Name: Modified PGK Device

Indications For Use:

Precise three-dimensional placement of needles ^{through a sterile field} into the human body for diagnostic and therapeutic purposes, including brachytherapy for prostate cancer

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David M. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K980997

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use