



# Northwest Radiation Therapy Products

a division of  
Real World Design & Development Company

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

### NORTHWEST RADIATION THERAPY PRODUCTS PRECISION STEPPER AND NEEDLE GUIDE

1. **Submitter's Name/  
Contact Person:** Terence Ellard  
  
**Company:** Northwest Radiation Therapy Products  
A Division of Real World Design and  
Development Company  
5245 Shilshole Avenue NW, Suite B  
Seattle, WA 98107  
  
**Telephone:** (206) 789-3380  
**Facsimile:** (206) 789-3202
2. **Name of Device:** Northwest Radiation Therapy Products Precision  
Stepper and Needle Guide  
  
**Classification:** Manual Radionuclide Applicator System  
21 CFR 892.5650; Product Code IWJ  
Class 1 (Radiology Panel)
3. **Predicate Device:** CIVCO Seed Implant Needle Guide (K875241)  
CIVCO Ultra-Step Stepper (K871413)
4. **Device Description:** The Precision Stepper and Needle Guide is a manually operated medical device used to provide mechanical support for the application of a radionuclide source into the prostate in the course of a brachytherapy procedure in a clinical setting. The Stepper guides and secures a rectal probe which is used for imaging of the prostate. The Stepper moves the transducer in precise increments, or steps. When used in conjunction with the Stepper, the Needle Guide is used to aid the clinician in guiding needles through a

template into the prostate. Under the guidance of the ultrasound probe, these needles are used to implant radioactive seeds that irradiate the prostate in cancer therapy.

5. **Intended Use:** The Precision Stepper and Needle Guide is intended for use with a rectal probe in ultrasound-guided radioactive seed implantation (transperineal prostate brachytherapy), and prostate gland voluming. The Precision Stepper and Needle Guide system is an accessory to an ultrasound system used for these medical procedures in a clinical setting.
6. **Comparison of Technological Characteristics:** We believe the Precision Stepper and Needle Guide to be substantially equivalent to the Stepper and Seed Implant Needle Guide manufactured by CIVCO Medical Instruments Company under 510(k) references K875241 and 871413. Both devices provide the means of mechanical support to hold an ultrasound rectal probe and provide guidance for isotope needles into the prostate. The devices are also substantially equivalent in their materials, design, principle of operation, and technology. As a manually operated system, there is no software component or energy source to the device.
7. **Standards:** No standards have been established for this device. The device is, however, manufactured in accordance with the U.S. Quality System Regulation, 21 CFR 820.
8. **Testing:** The Precision Stepper and Needle Guide has been subject to extensive inspection and testing to verify that the device meets all its physical and performance specifications. Test results are maintained in the design history file and/or device history files for this device.

In conclusion, the Precision Stepper and Needle Guide is as safe and effective as its predicate device and raises no new issues.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Terence R. Ellard  
NW Radiation Therapy Products  
5245 Shilsole Avenue, NW  
Suite B  
Seattle, WA 98107

Re: K973786  
NWRTP Precision Stepper and Needle Guide  
Dated: October 3, 1997  
Received: October 6, 1997  
Regulatory Class: I  
21 CFR 892.5650/Procode: 90 IWJ

JAN - 2 1998

Dear Mr. Ellard:

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 requirement, 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/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

# INDICATIONS FOR USE

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510(k) Number (if known): Not Known (New Submission)

Device Name: Northwest Radiation Therapy Products (NWRTP) Precision Stepper and Needle Guide

Indications for Use:

*Condition to be screened, monitored, treated or diagnosed.*  
Prostate gland voluming and treatment of prostate cancer by transperineal brachytherapy

*Prescription use only.*

Yes. Caution statement is provided in the labeling for this device.

*Parts of body applied to.*

None.

*Frequency of use.*

Frequency as directed by physician.

*Physiological purpose.*

The Precision Stepper provides equipment support and guidance for a rectal probe. When used with its Needle Guide, an ultrasonic imaging system, and a rectal probe, the Precision Stepper and Needle Guide System is an accessory to clinical procedures for prostate gland voluming and ultrasound-guided radioactive seed implantation.

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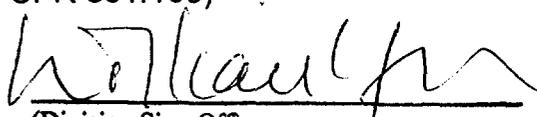
\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use    
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

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