OCT - 8 1996

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K960918

VIDAMED TUNA® (Trans Urethral Needle Ablation) System

Indication

The TUNA System 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.

Device Description

The TUNA® System consists of the TUNA® 3 Catheter, the VIDAMED Model 7205 RF Generator, the VIDAMED Return Electrode, the VIDAMED Rectal Monitoring Tape, and the TUNA® Optics.

The electrosurgical generator is capable of delivering up to 30W (15W/channel) of power and is designed for use with VIDAMED accessory electrodes including the TUNA® 3 Catheter. When used with VIDAMED accessory electrodes, the electrosurgical generator is capable of reading temperature from thermocouple sensors within the electrode and controlling power output to the tissue.

Substantial Equivalence

The VIDAMED TUNA® 3 Catheter and VIDAMED Model 7205 RF Generator is substantially equivalent to devices provided by VIDAMED (K951245 and K955035), and Radionics (pre-amendments). Information is provided in the premarket notification to demonstrate that the properties of the TUNA® 3 Catheter and VIDAMED Model 7205 RF Generator are equivalent to equipment from the manufacturers listed above. Confirmatory clinical data is also provided to support the safety and effectiveness of the device for use in the treatment of symptoms due to urinary outflow obstruction secondary to BPH.

Standards/Classifications

The VIDAMED Model 7205 RF Generator and accessories are designed to be in compliance with ANSI, AAMI, and UL 544 standards. The VIDAMED Model 7205 RF Generator and accessories are Class II medical devices.