

APR 30 1997

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS  
TUNA® 5 Catheter

K965199

Indication

The TUNA 5 Catheter is indicated for use as part of the VIDAMED TUNA System. The VIDAMED 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 VIDAMED TUNA System includes an RF generator and an accessory catheter for delivery of energy to the patient. The TUNA 5 Catheter contains two electrodes which can be deployed through a cystoscopic sheath at various angles between 0° and 90°, and various lengths between 14 and 22 mm. The needles are insulated at the base to protect the urethra during ablation of tissue.

Substantial Equivalence

The VIDAMED TUNA System is already cleared for the treatment of BPH. The TUNA 5 Catheter is substantially equivalent to two previously cleared VIDAMED accessory electrodes, the TUNA 3 Catheter which was cleared in 510(k) K960918, and the VIDAMED AEC which was cleared in 510(k) K951245.

Standards/Classifications

The VIDAMED TUNA System is a regulatory Class II medical device.