

JAN 28 1997

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
VIDAMED Model 7600 RF Generator

K965061

Indication

The VIDAMED Model 7600 RF Generator is indicated for use as part of the VIDAMED TUNA System to deliver RF energy and record patient treatment data. 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 Model 7600 RF Generator is capable of delivering up to 30W (15W/channel) of RF energy and is designed for use with VIDAMED accessory electrodes including the TUNA Catheter. When used with VIDAMED accessory electrodes, the VIDAMED Model 7600 RF Generator is capable of reading, recording, and storing data obtained from thermocouple sensors within the electrode. Software within the RF generator and controls the RF energy output to the tissue.

Substantial Equivalence

The VIDAMED TUNA System is already cleared for the treatment of BPH. The VIDAMED Model 7600 RF Generator is substantially equivalent to two previously cleared VIDAMED devices, the VIDAMED Model 7205 RF Generator, and the VIDAMED Model 7312 RF Generator Data Recorder. The VIDAMED Model 7600 RF Generator is substantially equivalent to the VIDAMED Model 7205 RF Generator which was cleared in 510(k) K960918. In addition, the features of the VIDAMED Model 7312 RF Generator Data Recorder previously cleared in 510(k) K963180 have been incorporated into the VIDAMED Model 7600 RF Generator.

Standards/Classifications

The VIDAMED TUNA Model 7205 RF Generator is designed to be in compliance with ANSI, AAMI and UL electrical safety standards. The VIDAMED TUNA System is a regulatory Class II medical device.