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K963180

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

VIDAMED RF Generator Data Recorder

Indication

The VIDAMED RF Generator Data Recorder is indicated for use in recording patient treatment data when used in conjunction with VIDAMED RF Generators such as the VIDAMED Model 7205 RF Generator. The data recorder software does not control or effect the output of power from the RF Generator, nor is it intended to be used in the treatment or diagnosis of any disease.

Device Description

The VIDAMED RF Generator Data Recorder is designed for use with VIDAMED RF Generators such as the VIDAMED Model 7205 RF Generator. When used with VIDAMED RF Generators, the VIDAMED RF Generator Data Recorder Software is capable of recording the lesion temperature, proximal shield (urethral) temperature, needle impedance, power delivered, and total energy delivered.

Substantial Equivalence

The VIDAMED RF Generator Data Recorder Software is considered an accessory to a previously cleared device. The VIDAMED RF Generator Data Recorder is designed solely for use with VIDAMED RF Generators such as the VIDAMED Model 7205 RF Generator which was previously cleared in 510(k) K955035.

Standards/Classifications

No performance standard(s) or special controls applicable to this device have been promulgated under Section 514 of the Act.