

K963901

Smith & Nephew Endoscopy, Inc.

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510(k) Summary

Smith & Nephew Endoscopy Endoscopic Electrosurgical Probe and Handle

Substantial Equivalence :

The Smith & Nephew Endoscopy Disposable Endoscopic Electrosurgical Probe and Handle were originally determined to be substantially equivalent to pre-amendment devices under 510(k) K901505..

Predicate Device :

The change discussed in this 510(k) does not affect the method of use, or intended use, of the device. The additional labeling of a voltage limit is a European requirement for CE marking. Other changes to this device are user convenience features only.

Summary of Device Function :

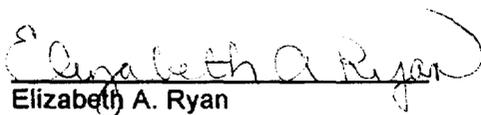
Smith & Nephew Endoscopy Endoscopic Electrosurgical Probe and Handle is used in conjunction with an electrical generator to excise tissue and coagulate bleeding.

Intended Use of Device :

Excise tissue and coagulate tissue.

Comparison of Technological Characteristics of Predicate Device :

The design technologies and function of the items referred to in this 510(k) notification are identical to those listed in the previous Electrosurgery Probe 510(k) submitted by Smith & Nephew Endoscopy, Inc.


Elizabeth A. Ryan
Regulatory Affairs

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