

K945586

I. 510(K) SUMMARY

Submitted By:

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Device:

Trade Name:	Flexible Dilating Sheath
Common/Usual Name:	Vessel Dilator, Catheter Dilator
Proposed Classification:	Vessel Dilator for Percutaneous Catheterization 21 CFR Part 870.1310 (74DRE)

Predicate Devices:

The Flexible Dilating Sheath is similar to predicate dilating sheaths manufactured by Cook Pacemaker Corporation.

Device Description:

The Flexible Dilating Sheath is intended for percutaneous dilation of tissue surrounding indwelling catheters or foreign objects. The device is supplied sterile and is intended for one-time use. Reasonable assurance of biocompatibility of the materials comprising the Flexible Dilating Sheath is provided by their established history of use in medical product manufacturing. Results of toxicity testing also provide reasonable assurance of biocompatibility, with the results showing the material to meet the test requirements.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program, undergoing packaging and sterilization procedures similar to devices currently marketed and distributed by Cook Pacemaker Corporation. This device is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510(k) substantial equivalency.