

K960698

I. 510(K) SUMMARY

Submitted By:

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Device:

Trade Name: Non-Coring Needle

Common/Usual Name: Non-Coring Needle,
Huber-Type Needle, Tip-
Deflected Needle, Septum
Needle

Proposed Classification Name: Hypodermic Single Lumen
Needle, 21 CFR Part
880.5570 (80FMI)

Predicate Devices:

The Non-Coring Needle is similar to predicate non-coring needles that are currently marketed, having the same intended use of penetrating the septum of subcutaneous access ports, and being of similar technology, having a stainless steel cannula and Luer hub.

Device Description:

The Non-Coring Needle is used for accessing a subcutaneous port to administer or withdraw fluids. The device is supplied sterile and is intended for one-time use. Reasonable assurance of biocompatibility of the materials comprising the Non-Coring Needle is provided by their established history of use in medical product manufacturing.

Substantial Equivalence:

The Non-Coring Needle 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.