

K960262

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510(k) Premarket Notification
Coring Morcellator
Cook OB/GYN

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I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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Submitted By:

Tammy Bacon
Cook OB/GYN
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-6500
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Device

Trade Name: Coring Morcellator
Proposed Classification Name: Laparoscope, Gynecologic (and Accessories)

Predicate Devices:

The Coring Morcellator is substantially equivalent to other predicate devices in terms of indications for use and technology. Predicate devices include the Serrated Edged Macro Morcellator (S*E*M*M*-Set) manufactured by Wisap and the Birtcher Endoscopic Corkscrew manufactured by Birtcher Electro Medical Systems.

Device Description:

The Coring Morcellator is used during laparoscopic surgery for the removal of a non-malignant fibroid tumor or other tissue within the peritoneal cavity. This device will be made from stainless steel. Stainless steel is widely accepted in the medical field, therefore, biocompatibility is assured.

Substantial Equivalence:

This device will be manufactured according to specified process controls and a Quality Assurance Program. This device will undergo packaging and sterilization procedures similar to devices currently marketed and distributed by Cook OB/GYN. Being similar with respect to indications for use, materials and physical construction to predicate devices, this device meets the requirements for section 510(k) substantial equivalence.