

APR 17 1996

ATTACHMENT A
510(k) SUMMARY
PAGE 1 of 2**Submitter's Identification:**

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Name of the Device:

CODAN Spike Vial Adapter

Predicate Device Information:

Acacia Transfer Pins and Micron Filter (K901063)
B. Braun Mini-Spike® Dispensing Pin™ (K925401)

Device Description:

The Codan Spike is a sterile, nonpyrogenic, multiple dose vial adapter for the preparation and withdrawal of medications and cytotoxic solutions. The Codan Spike contains a 0.20 µm pressure resistant hydrophobic filter that is pressure stable and hydrophobic.

Intended Use:

The CODAN Spike is designed to be used to transfer medication from a vial to a syringe and from syringe to an IV set.

Comparison to Predicate Devices:

The CODAN Spike is substantially equivalent to the Acacia Luer Lock Transfer pin and to the Braun Mini-Spike® Dispensing Pin™. The CODAN Spike and the predicate devices are constructed from the same materials and similar in design and intended uses.

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Conclusion:

The CODAN Spike is a sterile nonpyrogenic disposable device that is made of identical materials as the legally marketed predicate devices (Acacia Luer Lock Transfer Pin and the Braun Mini-Spike® Dispensing Pin™), with similar indications for use, and is identically processed and sterilized.