

APR 30 1996



916-342-4133
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23 April 1996

510(K) SUMMARY

The 510(k) summary information required by 21 CFR 807.92 is as follows:

- A. Classification name: Set, biopsy needle and needle, gastroenterology, or instrument, biopsy
 Common/usual name: Biopsy needle
 Proprietary name: Daum BiopsyNeedle
- B. Substantial equivalence: Baxter (Pharmaseal) TruCut (K813338), MD Tech Ultra-Core Biopsy Needle, and others.
- C. Device description: The Daum BiopsyNeedle is a standard soft-tissue biopsy needle.
- D. Intended use: The Daum BiopsyNeedle is intended for use in percutaneous or open surgical biopsies, including but not limited to, biopsy of breast, lung, kidney, liver, lymph nodes, and prostate.
- E. Technological characteristics: The Daum BiopsyNeedle is similar to predicate devices

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in its design, function, and intended use.

The proposed device is different than many biopsy needles in that the Daum device has components manufactured of titanium and titanium alloys, rather than from stainless steel.

Submitted,
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