



Medical Products and Services

K 96 2568

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SUMMARY OF SAFETY AND EFFECTIVENESS

OWNER: Gallini s.r.l.
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41037

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SUBMISSION DATE: April, 1996

DEVICE NAME: ACRI®-Iliac Crest Aspiration-Biopsy Needle

PREDICATE DEVICE: Promedical - Jamshidi style biopsy needle

INTENDED USE: The device is intended to be used for drawing osteomedullary substances from the iliac crest.

DESCRIPTION OF FUNCTION: A manually operated, biopsy needle used for aspiration or explantation of bony substance.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The ACRI® needle is equivalent to the predicate device in terms of technological characteristics and function.

The following tests were performed to demonstrate the safety, performance and efficacy of the product;

TEST	RESULT
Intracutaneous Reactivity	Passed
Acute Systemic Toxicity	Passed
Pyrogen Test	Passed
Cytotoxicity	Passed