

NOV 27 1996



Medical Products and Services

K 962569

SUMMARY OF SAFETY AND EFFECTIVENESS

OWNER: Gallini s.r.l.
88/90 Via S. Faustino
Mirandola, Italy
41037

CONTACT: Paul L. Hawthorne
U.S. Representative
C/O Coeurage Enterprises
3106 Bretton Court
Glen Allen, VA 23060

SUBMISSION DATE: April, 1996

DEVICE NAME: BIOMID® - Bone Marrow Biopsy Needle

PREDICATE DEVICE: Promedical - Jamshidi style biopsy needle

INTENDED USE: The device is intended to be used for drawing osteomedullary substances and/or the explantation of bone marrow.

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