



NOV 27 1996

Medical Products and Services

K962570

### 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: ISAN®-Sternal-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 sternum or 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 ISAN® 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