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Attachment VII:

Summary of Safety and Effectiveness Information [510(k) Summary]

Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Angela Silvestri October 20, 1995

Device: Synthes Cannulated Femoral Nail (CFN) System is compared to Synthes Unreamed Femoral Nail (URFN).

Synthes CFN is intended to stabilize fractures of the femur. Specifically, it is intended for acute femoral diaphyseal fractures, post-isthmic femoral fractures, subtrochanteric femoral fractures, non-unions, and impending pathological fractures. Synthes CFN is a cannulated locking intramedullary fixation device. It is cannulated throughout the length of the nail which facilitates insertion over a guide rod into a reamed or unreamed femur. The nail has a gradual anterior bow with a radius of curvature that is designed to approximate that of the femur. It has proximal and distal locking holes that utilize the same size locking bolts. The most proximal locking hole is elongated. Nail accessories include a Twisted Blade, 5.0 mm Shaft Screws, Locking Sleeves, 4.9 mm Locking Bolts, and End Caps. The accessories are intended to transmit load between the bone and the CFN to prevent rotation and displacement of the nail/fracture when stabilizing subtrochanteric femoral fractures. The device is manufactured from titanium alloy.

Synthes URFN is intended to stabilize fractures of the femur. Specifically, it is intended for acute femoral diaphyseal fractures, post-isthmic femoral fractures, subtrochanteric femoral fractures, and impending pathological fractures. The Synthes URFN is also intended to stabilize fractures of the femur. Specifically, it is intended for acute femoral diaphyseal fractures and post-isthmic femoral fractures. The nail has a gradual anterior bow with a radius of curvature that is designed to approximate that of the femur. It has proximal and distal locking holes that utilize the same size locking bolts. The proximal-most locking hole is elongated. It has a solid cross section to facilitate insertion into a non-reamed or minimally reamed femur. The device is manufactured from titanium alloy.

Synthes will provide the device both sterile and non-sterile. Of course, non-sterile devices must be sterilized prior to use; moist heat sterilization is recommended using the Association for the Advancement of Medical Instrumentation (AAMI) guideline "Good Hospital Practice: Steam Sterilization and Sterility Assurance".

Based on mechanical test results, the CFN design has been found to be at least equivalent to the URFN.

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