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ATTACHMENT VII:

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

Synthes (USA)
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Device: Synthes FlexNail is compared to the Applied Osteo Systems, Inc. TrueFlex Humeral Nail.

The Synthes Flexible Humeral Nail [FlexNail] is intended for treatment of humeral shaft fractures; specifically, it is intended for treatment of acute humeral shaft fractures, including certain pre- and post-isthmal fractures (including, but not limited to transverse, short oblique, long oblique, butterfly, and segmental fractures, of all grades of comminution); pathologic or impending pathologic fractures; and non- and malunions of the humeral shaft. The nail is comprised of a central connecting wire, four peripheral wires, solid segments (each of which is round in cross section and is centrally cannulated to hold the central connecting wire), and a tension block. Nail accessories include a cortex screw with self-tapping flutes, for nail interlocking; a tension screw that mates with the tension block; and end caps. It is straight throughout most of the length, with a 30° bend located near the proximal end; it has a bullet-shaped distal end. It has proximal, distal and longitudinal holes to accept screws and wires. The device is manufactured from Titanium-6% Aluminum- 7% Niobium.

The Applied Osteo Systems, Inc. TrueFlex Humeral Nail is also intended to treat fractures of the humeral shaft. Specifically, it is intended for humeral shaft fractures of all patterns, within a range from 3cm distal to the surgical neck to 5cm proximal to the olecranon fossa: transverse, short oblique; long oblique; butterfly; segmental and all grades of comminution. The nail is solid, with a five-fluted star cross section, is straight throughout the entire length, and is bullet-shaped distally. Locking is provided via a screw end cap. The nail is manufactured from Titanium-6% Aluminum-4% Vanadium.

Both nails are designed to function as non-reamed, flexible and locking intramedullary devices, capable of sharing normal weight-bearing forces/load with the fixed fractured humerus. Both nails lock within the medullary canal at either end of the bone, bridging the fracture and maintaining alignment while the fracture heals. In this function, the nails control most of the torsional and shear forces that would otherwise be transferred to the fracture site, while providing axial locking to prevent either fracture distraction or shortening. The nails are both inserted without a guide wire, and are primarily intended to be inserted without pre-reaming the medullary canal, reducing damage to endosteal blood supply.

Synthes FlexNail is at least equivalent to the Applied Osteo Systems, Inc. TrueFlex Humeral Nail, based on the results of the testing of both devices.