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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM: DePuy Inc.
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Warsaw, Indiana 46581-0988

510(K) CONTACT: Cheryl Hastings
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TRADE NAME: Sterile Kirschner Wires and Steinmann Pins

COMMON NAME: Bone Fixation Fasteners

CLASSIFICATION: 888.3040 Smooth or threaded bone fixation fasteners

DEVICE PRODUCT CODE: 87 HTY and 87 JDW

SUBSTANTIALLY EQUIVALENT DEVICES: DePuy Non-sterile Kirschner Wires and Steinmann Pins

INTENDED USE AND DEVICE DESCRIPTION:

The Sterile Kirschner Wires and Steinmann Pins are indicated for use in fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeletal system.

This system consists of sterile, smooth and threaded Kirschner wires (K-wires) and Steinmann pins ranging in length from 4 to 9 inches and ranging in diameter from 0.028 to 0.188 inches. All of the K-wires and Steinmann pins except the 6" K-wires are available with four point style options: trocar, bayonet, double end trocar and double end bayonet. The 6" K-wires are available with double end trocar points. All of the K-wires and Steinmann pins are manufactured from 316 LVM stainless steel.

BASIS OF SUBSTANTIAL EQUIVALENCE:

A comparison of the sterile K-wires and Steinmann pins described in this submission and the non-sterile devices sold prior to 1976 shows that they are very similar or identical in terms of design, sizes, material and intended use. The only significant difference between the two systems is that the system described in this submission is provided sterile while the system sold by DePuy prior to 1976 was non-sterile.

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