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Attachment 3: Summary of Safety and Effectiveness Information [510(k) Summary]

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Device Name: Synthes Schuhli Implant System is compared to Synthes Dynamic Compression Plates and screws.

The Schuhli Implant System is intended for use with Synthes long bone and small bone plates and screws. The Schuhli Assembly locks the screw to the plate (independent of bone contact) and has the potential to decrease the possibility of the screw loosening and backing out of the bone. The devices are designed for, but are not limited to, use in osteoporotic bone for unicortical (of the far cortex) or bicortical fixation in cases of trauma, tumor, or infection, and as fixed angle devices (where the angle between two supporting members is fixed).

The Schuhli Implant System consists of a nut, a washer, and a temporary holding screw. The nut fits into the underside of the plate and has spikes which secure the nut to bone. The temporary holding screw is used to hold the Schuhli to the plate (before the screws are placed) while the surgeon obtains the correct placement of the plate. The washer fits into the plate's screw hole, accepting the head of a screw. The Schuhli Implant System is available in two sizes (4.5 mm and 3.5 mm); each size is available in either titanium or stainless steel, and is used with either titanium or stainless steel compression plates and screws, respectively.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Synthes Schuhli Implant System will be provided to the user sterile. Gamma radiation will be used to sterilize the device.

Based on mechanical test results, the Schuhli Implant System is substantially equivalent to Synthes Dynamic Compression Plates and screws.