



K961421

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

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Device: Synthes 2.4 mm Universal Locking Plate System, as compared to Synthes 2.7 mm Reconstruction Plate System.

The Synthes 2.4 mm ULPS is a plate and screw system, that is intended for mandible trauma and reconstruction procedures.

The plates attach to bone via self-tapping cortex and/or locking screws, and are available in various shapes and sizes. The plates feature compression screw holes that are internally threaded to accept the 2.4 mm - 3.0 mm locking screws.

The following instrumentation is used with the 2.4 mm ULPS:

Threaded Drill Guide is used for guiding the drill bit to bone by threading the tip into the plate's screw hole. The bore (inside diameter) of the drill guide is dependent upon the screw size when selected since each screw diameter requires a specific drill diameter. They are available with bores from 1.5 mm to 2.5 mm.

2.4 mm Insert Screw is used by the surgeon while bending the plate to avoid deforming the threaded screw holes. The inserts are screwed into the plate holes prior to bending and removed once the bending operation is complete.

Synthes will provide the device 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, we believe that the devices are at least equivalent.