

Attachment D:

K964416

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

SYNTHES (U.S.A.)
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Device:

SYNTHES (U.S.A.) Universal Spinal Rod, and Screw Fixation System Parallel Connector compared to the Acromed Kaneda SR (Smooth Rod) Anterior Spinal System Transverse Couplers.

The Synthes Universal Spinal Rod and Screw Fixation System consists of rods, and 6, 7, and 8 mm diameter side-opening screws with a collar and nut. The system also includes a staple, a washer and a parallel connector. The Universal Spinal side-opening screws attach to the anterolateral portion of the vertebral body of the thoracolumbar spine (levels T8-L5) and are connected via a rod.

The SYNTHES (USA) Universal Spinal Parallel Connector is part of the Universal Rod and Screw Fixation System and is intended for anterolateral screw/staple fixation for the correction of anterolateral lordotic deformities of the spine, lumbar scoliosis, pseudoarthrosis, and fracture or dislocation of the thoracolumbar spine, (levels T8-L5).

The Acromed Kaneda SR (Smooth Rod) Anterior Spinal System has the same intended use and is also indicated for correction of anterolateral lordotic deformities of the spine, lumbar scoliosis, pseudoarthrosis, and fracture or dislocation of thoracolumbar fractures like the Universal Spinal Parallel Connector.

The Acromed Kaneda SR (Smooth Rod) Anterior Spinal is manufactured from certified Implant Grade stainless steel and a titanium alloy (Ti-6Al-4V). This system is similar in component dimensions and sizes to the SYNTHES (U.S.A.) Universal Spinal Parallel Connector.

The Synthes Universal Spinal Rod and Screw Fixation System Parallel Connector is provided non-sterile; moist heat sterilization is recommended.

Based on the above, the SYNTHES (U.S.A.) Universal Spinal Parallel Connector is substantially equivalent to Acromed Kaneda SR (Smooth Rod) Anterior Spinal System.