

K963614

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510(k) Summary

Trade Name: Monotube® Carbon Tube
Common Name: External Fixation Tube
Classification Name: Smooth or Threaded Metallic Bone
Fixation Fastener 888.3040

The Monotube® Carbon Tubes, previously cleared in a premarket 510(k) submission, are connecting elements for use with the Monotube® Clamps for the construction of external fixation frames. The tubes are available in 15mm, 20mm and 25mm diameters and a variety of lengths to accommodate varying anatomical situations. This present submission describes a change in material and manufacturing method to these tubes.

Equivalency of this device is based on similarities in intended use, materials, design and operational principles to the previously cleared Monotube® Carbon Tubes.

Testing of the devices is presented in the submission. Testing was performed to compare the static mechanical properties of the tube and subassemblies using both the existing tubes and the tubes that are the subject of this submission. Static axial compressive frame testing was also performed to determine frame yield strength and stiffness.

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