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510(k) SUMMARY

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Device: Forefoot Reconstruction System

Proprietary Name: Forefoot Reconstruction System

Common Name: Small Bone Screw System

Classification Name and Reference: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories 888.3030

Proposed Regulatory Class: Class II

Device Product Code: 87HRS 763EY

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The Forefoot Reconstruction System is a series of Ti6Al4V titanium alloy screws 2.3-3.0 mm in diameter and 8-22 mm in length. The system is intended for use in internal fixation of small bones including the foot, hand, craniofacial skeleton and midface. All screws are fully threaded and self-tapping with internal hex-drive heads.

The substantial equivalence of these devices is based on equivalence in intended use, design, materials and operating principles to several legally marketed devices including the Luhr[®] Fixation System (Howmedica Inc.), the Alta[®] Modular Trauma Small Bone Plating System (Howmedica Inc.) and the Synthes[®] Small Fragment and Mini Set (Synthes USA).