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510(k) SUMMARY

Device: Profyle™ Hand and Small Fragment System

Proprietary Name: Profyle™ Titanium Hand and Small Fragment System

Common Name: Small Bone Plating 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

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The Profyle Hand and Small Fragment System is a series of titanium plates and screws with plates of varying lengths and thicknesses and configurations including straight, L, T, Y, Z, rectangular, and condylar head options. The system is intended for use in internal fixation of small bones including the hand, foot, and craniomaxillofacial skeleton. These plates are attached to bone using 1.2-2.7 mm diameter titanium bone screws; screw diameter is dependent upon plate thickness. All screws are fully threaded and self-tapping with cross-slotted 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), the Synthes® Small Fragment and Mini Set (Synthes USA) and the Wurzburg® Titanium Mini Bone Plates and Screws (Howmedica Leibinger Inc.).

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