

ACUMED™

Quality Orthopaedic Instruments and Implants

Enclosure D - 510(k) Summary

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This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.93.

The Acumed Bone Grafting System is a set of various size drills, a Hudson adaptor fitting, a starting punch, a bone plug extractor, and a removal key. A manual drill handle will be added to the system eventually so that the drills may be operated manually. The Hudson adaptor fitting attaches to a standard DC-powered surgical drill. The drill size is selected and attached to the adaptor. The starting punch dimples the bone so a reference point for the drill tip is made. After drilling and harvesting the bone, the drill assembly is removed. The drill piece is detached with the removal key and the bone material is extracted or pushed out by the plug extractor.

The Acumed Bone Graft System is manufactured from 17-4 ph stainless steel. The instruments are provided non-sterile. Data that validates a set of recommended steam sterilization process parameters which obtain a resulting SAL of 10^{-6} are maintained on file at Acumed. Information regarding implantation, packaging, and labeling have been provided.

The Acumed Bone Graft System is similar to Wright Medical Technology's Precision Bone Grafting System in form, function, composition, and indications and is expected to perform as well as similar devices.