

K970040

510(k) Summary

FEB 28 1997

Spine-Tech Bone Harvester

General Information

Classification	Class I
Trade Name	Spine-Tech Bone Harvester
Submitter	Spine-Tech, Inc. 7375 Bush Lake Road Minneapolis, MN 55439-2029 (612) 832-5600
Contact	David A. Cannistraci Director of Regulatory Affairs (612) 832-5600

Predicate Devices

Acumed Bone Graft System
Spine-Tech Bone Harvester, Non-Powered
General and Orthopedic Surgical Instruments, Accessories/Attachments

Intended Use

The Spine-Tech Bone Harvester is indicated for the cutting and collection of morselized autogenous bone graft from the anterior or posterior iliac crest, tibia or femur.

This device is intended to cut and collect finely morselized autogenous bone graft for any surgical procedure requiring bone graft to facilitate fusion and/or fill bone defects. These procedures include; spinal fusion, joint arthrodesis, total joint replacement, fracture repair, maxillofacial reconstruction and tumor removal.

All components of the Spine-Tech Bone Harvested are intended for single use only.

Device Description

The Spine-Tech Bone Harvester consists of two cutting head/collection tube sizes, Hudson or Hall fitting adapter for power use, trocar and plunger. The cutting heads and trocar are constructed from stainless steel. The collection tube and adapter are constructed from medical grade polycarbonate. The plunger is constructed from acetal copolymer.

After cutting and collection of morselized bone graft, the cutting head is removed from the collection tube with the trocar and bone is pushed out of the collection tube with the plunger.

Testing

Biocompatibility testing has been performed on the materials used in the construction of this device and is documented in the ASTM Standard.

Performance and quality testing of the product included bench testing, dimensional and workmanship inspection. All testing of the device yielded acceptable results.

Summary of Substantial Equivalence

The Spine-Tech Bone Harvester is substantially equivalent in material, design, and function to Acumed Bone Graft System and other general and orthopedic surgical instruments used for the harvesting of autogenous bone.

Due to the similarity of materials and design to both pre-enactment and post-enactment devices, Spine-Tech believes that the Spine-Tech Bone Harvester does not raise any new safety or effectiveness issues.