Enclosure D - 510(k) Summary

FEB 19 1997

K965029

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 Stableloc II External Fixation System consists of an external fixation device and a selection of threaded guide pins. The external fixator is not intended for implantation, only as a tool in surgery. It holds in place the pins which provide fracture reduction and alignment. The Stableloc II External Fixation System is used to address Colles' fractures and distal radial osteotomies and is not intended for use in the spine. The Stableloc II External Fixator is manufactured from Ultem, aluminum, stainless steel, and titanium while the guide pins are made from stainless steel per ASTM F 138. The external fixator is provided non-sterile. Acumed has identified a set of process parameters for steam sterilization which provide an SAL of 10^{-6} as validated by data on file at Acumed. The guide pins are provided sterile. Sterility is achieved by a minimum of 2.5 megarads gamma radiation. Verification of sterility is performed with the AAMI - Method 1. Sterility level is 10^{-6}. We make no claims as to the pyrogenicity of this product. Information regarding packaging and labeling has been provided.

The Stableloc II External Fixation System is similar to EBI Medical System's Orthofix Dynamic Axial Fixation System in material, intended use, and design. Each system's guide pins are manufactured from stainless steel. Both devices are intended to be used for Colles' fractures and distal radial osteotomies. Both devices are designed to hold two proximal and two distal guide pins and allow the pins to be adjusted. Also, the surgical techniques of both devices are similar. Based on the similarities between the Stableloc II External Fixator and the Orthofix Dynamic Axial Fixator, the safety and effectiveness is expected to be similar to the orthofix Dynamic Axial Fixator.

