SYNTHES®

MAY -9 1997

Attachment II: **SUMMARY OF SAFETY AND EFFECTIVENESS FOR SYNTHES (U.S.A.) POLYPIN**

K961608

1. **SPONSOR NAME AND ADDRESS**

Synthes (U.S.A.)
P.O. Box 1766
1690 Russell Road
Paoli, PA 19301
TEL: (610) 647-9700

Contact Person:
Angela Silvestri
Manager, Regulatory Affairs

2. **DEVICE NAME**

Common/Usual Name: Bone Fixation Pin

Proprietary Name: Synthes (U.S.A.) Polypin

3. **CLASSIFICATION**

Bone Fixation Pins have been classified as Class II Orthopedic Devices under 21 CFR 888.3030.

4. **INTENDED USE**

The Polypin is intended for use in the fixation of small bone fragments in cases of low-load fractures, such as apical fragments, osteochondral fragments and cancellous/non-load-bearing fragments. Specific applications include the following:

Apical fragments:	radial head patellar rim navicular metacarpal/metatarsal (proximal or distal ends)
Osteochondral fragments:	talus vault femoral condyle
Spongy/non-load bearing fragments:	talus

5. **DEVICE DESCRIPTION**

The Polypin is a 2 mm diameter pin of high molecular weight absorbable poly (L/D-lactide). The Polypin is provided with a length of 35 mm, which can be shortened intraoperatively to as little as 10 mm. Eleven ring-shaped ribs, placed

at intervals of 2.5 mm on the pin, prevent the implanted pin from slipping out. The small, lens-shaped head of the Polypin permits the pin to be pushed down until it is completely below the surface of the cartilage or bone, permitting low load compression of the bone fragments. The Polypin is provided presterilized by gamma radiation and is not intended to be resterilized by the user.

6. SUBSTANTIAL EQUIVALENCE

The Polypin is substantially equivalent to preamendment, Class II metallic implants, such as Kirschner wires and small screws, used for the fixation of bony fragments. The Polypin is also substantially equivalent to other absorbable bone pins, such as the Johnson & Johnson OrthoSorb® Absorbable Pin, made of polydioxanon, and the Biosciences, Inc. BIOFIX® Bioabsorbable Pin, made of self-reinforced polyglycolide.

The determination of substantial equivalence was based on extensive in-vitro and in-vivo testing of the Polypin.