



Landos Inc. K962236

A SUBSIDIARY OF GROUP LANDANGER CAMUS

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3. SUMMARY OF SAFETY AND EFFECTIVENESS

MANUFACTURER IDENTIFICATION: Medinov - AMP
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FRANCE

SPONSOR IDENTIFICATION LANDOS INC.
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ESTABLISHMENT REGISTRATION NUMBER: 2530066

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DATE OF PREPARATION OF THIS SUMMARY: May 22, 1996

TRADE NAME: SCARF THREAD-HEAD™ SCREW

COMMON NAME: Bone Fixation Screw

CLASSIFICATION NAME AND REFERENCE: Screw, Fixation, Bone
(21 CFR, Section 888.3040)

PROPOSED REGULATORY CLASS: Class II

DEVICE PRODUCT CODE: 87HWC

PANEL CODE: 87OR

DESCRIPTION OF DEVICE:

The **SCARF THREAD-HEAD™ SCREW** is a cannulated thread-head screw made of a Titanium alloy. Screws come in lengths of 10-32 mm in 2 mm increments.

INTENDED USE:

The **SCARF THREAD-HEAD™ SCREW** is intended to be implanted for fixation of bone fractures or bone reconstructions.

INDICATIONS FOR USE:

The **SCARF THREAD-HEAD™ SCREW** is indicated for fixing the elective osteotomies of the mid-foot bones and the metatarsal and phalanges of the foot only.

PREDICATE DEVICE:

The **SCARF THREAD-HEAD™ SCREW** is substantially equivalent to the Medinov-AMP Scarf Screw (K931155), the Herbert-Whipple Bone Screw (Zimmer) (K792022) and the M3 Screw System (Osteomed) (K924018, 924138).

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Both the **SCARF THREAD-HEAD™ SCREW**, the Scarf Screw and the Herbert-Whipple Bone Screw have the same intended use and all are indicated for fixing small fractures or osteotomies. All are made from Titanium alloys. The **SCARF THREAD-HEAD™ SCREW** and Scarf Screws are threaded on nearly all their length with the same thread pitch. Both have a thread head and a hexagonal socket. The Scarf screw is not cannulated; the Herbert-Whipple screw is cannulated and is topped with a hexagonal socket.

SUMMARY OF STUDIES:

Rupture torque of the **SCARF THREAD-HEAD™ SCREW** was compared with requirements of the French Standard N° NF-F-90-414 and found to have a resistance to torsion in compliance with the selected Standard.