

SEP - 6 1996

K962644

**SUMMARY OF SAFETY AND EFFECTIVENESS
VIGOR COMPRESSION HIP SCREW SYSTEM**

I. General Information

Classification Name: Device, Fixation, Proximal Femoral Implant
Common Name: Compression Hip Screw
Device Trade Name: Vigor Compression Hip Screw System
Classification Code: 87JDO
Submitter's Name & Address: Deutschland Surgical Incorporated
1222 Commerce Street, Suite #415
Dallas, Texas 75202-4306
Establishment Registration No: 1646853
Contact Person: Thomas Wolter
Summary Preparation Date: July 5, 1996

II. Predicate Device

The Vigor Compression Hip Screw is claimed to be substantially equivalent in material, design, and function to the Synthes Dynamic Hip Screw cleared by FDA under 510(k) K791619 on August 28, 1979.

III. Device Description

The Vigor Compression Hip Screw System is intended as a means of rigid internal fixation for fractures of the proximal femur. The Vigor System implants consist of Bone Screws; Compression Screws, Lag Screws and Side Plates, and are offered in a wide, incremental range of sizes to ensure optimum selection for a proper fixation. The Vigor full-length threaded Bone Screws and Compression Bone Screws are available in a range of sizes from 22.0 mm to 60.0 mm in length. Vigor Lag Screws and Super Lag Screws feature a flattened, square base that engages the inner surface of the implant barrel for increased rotational stability. These Lag Screws are available in a range of sizes from 50.0 mm to 150.0 mm in length, in 5.0 mm increments. And, finally, a trio of low-profile Side Plates are included in the system. Vigor offers the standard 4-hole, 5-hole and 6-hole plates, each available in a 135°, 140° or 145° configuration.

The Vigor System instrumentation set consists of the standard instrumentation required for each indicated procedure.

Premarket Notification:
Vigor Compression Hip Screw

Deutschland Surgical Incorporated:
Submitted: July 5, 1996

IV. Sterilization

Vigor Implants and Instrumentation are provided non-sterile. Implants are for single use only. Both implants and instruments must be sterilized prior to use in accordance with the recommended sterilization parameters described in the package insert in order to achieve a sterility assurance level of 10^{-6} .

V. Indications for Use

The Vigor Compression Hip Screw is indicated as a means of rigid internal fixation of stable and unstable fractures of the proximal femur in which a stable medial buttress can be reconstructed and is intended for the management of intertrochanteric, subtrochanteric and basilar neck fractures and selected trochanteric non-unions.

VII. Substantial Equivalence

The Vigor Compression Hip Screw System is considered to be substantially equivalent to the Synthes Dynamic Hip Screw[K791619] distributed by Synthes (U.S.A) at 1690 Russell Road, Paoli, PA 19301.

Feature	Vigor Compression Hip Screw	Synthes Dynamic Hip Screw
Material	316L Stainless Steel	316L Stainless Steel
Design	Bone, Compression and Lag Screws, low-profile, angled side plates and associated instrumentation.	Bone, Compression and Lag Screws, low-profile, angled side plates and associated instrumentation
Function	Rigid internal fixation to fractures of the proximal femur.	Rigid internal fixation to fractures of the proximal femur.

VIII. Conclusion

The Vigor Compression Hip Screw System is considered to be substantially equivalent in design, material and function to the Synthes Dynamic Hip Screw and is believed to perform as well as the Synthes System.