

k 960805

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510(k) SUMMARY OF INFORMATION:

SUBMITTER:

United States Surgical Corporation
150 Glover Avenue
Norwalk, CT 06856
(203) 845-1000

CONTACT PERSON:

Janet G. Johnson

DATE PREPARED:

February 27, 1996

CLASSIFICATION NAME:

Arthroscope

COMMON NAME:

Arthroscope

PROPRIETARY NAME:

Trademark name not yet determined.

DEVICE DESCRIPTION:

The Auto Suture* Arthroscope** is a reusable arthroscope which has a 30° field of view and a diameter maximum of 4.75 mm. The device utilizes a fiber optic light transmission system to illuminate the joint capsule and an optical system to view the capsule.

PREDICATE DEVICE:

Auto Suture* Disposable Arthroscope** (K933576)

INTENDED USE:

Both the Auto Suture* Arthroscope** and the Auto Suture* Disposable Arthroscope** (K933576) are intended to be used in orthopedic surgery for the arthroscopic illumination and viewing of joint capsules.

MATERIALS:

Both the Auto Suture* Arthroscope** and the Auto Suture* Disposable Arthroscope** (K933576) are comprised of biosafe materials, such as stainless steel, ABS plastic, and aluminum.