SEP 11 1996

SUMMARY OF SAFETY AND EFFECTIVENESS
American Microptiks, Inc. "AMO Arthroscope"
501K Number K962330
Updated as of September 6th, 1996

1. Submitter information:

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2. Device Name:

Classification Name: Arthroscope
Proprietary Name: AMO Arthroscope

3. Predicate Device:

An equivalent device to the AMO Arthroscope is the Storz (Karl Storz) 7200BW Arthroscope, manufactured in Germany at:

Mittelstrasse 8
D-4200 Tuttlingers
Postfach 230

This device is distributed in this country by Karl Storz Endoscopy - America, Inc, Charleston MA.

The above identified equivalent device uses the same basic design principles and technological features as the proposed AMO Arthroscope.

4. Description of Device:

The AMO Arthroscope is a device that will be provided non-sterile for arthroscopic procedures. The device has a basic design similar to those already sold legally in the U.S.A. Its construction consists of an eyepiece, body, light guide and a shaft. The shaft contains an outer tube, an inner tube, with light-carrying fibers sandwiched between these tubes. The inner tube contains the optical system.

5. Indications for Use:

Like other legally marketed arthroscopes, the AMO Arthroscope is indicated for use in minimally invasive procedures of the knee, shoulder and ankle joints, for joint examination, biopsy, arthroscopy, diagnosis of joint disease.

The device provides a clear view of the joint structures such as femoral condyles, medial meniscus, cruciate ligament, and other anatomical structures.

6. Description of Safety and Substantial Equivalence:

The biological safety of the AMO arthroscope has been defined through the selection of materials that demonstrated appropriate levels of bio-compatibility. The proposed AMO Arthroscope was designed with similar base materials. These materials are similar to those used in other legally marketed brands of arthroscopes, including the predicate device which is marketed for the same indications.

In summary, biocompatibility, function and device design have been developed to ensure the device is safe, effective, and substantially equivalent in materials, function and intended use to commercially available arthroscopes.

The device will be sold non-sterile, to be sterilized prior to each procedure by the user. Our recommended sterilization method, to be validated, is ethylene oxide gas.