

K960872

February 28, 1996

MAY -7 1996

**510(k) Summary**

**Submitter: Pollux Endoscopy, Inc.  
Address: 4696 NW 103rd Avenue  
Sunrise, FL 33351**

**Voice: (954) 748-8002  
Contact: Precious Resch**

**Device: Cystoscope 0/15/30/70 degrees 2.7mm/4mm  
Classification: Rigid Endoscope  
Common/Usual Name: Rigid Cystoscope/Resectoscope**

**Name of device to which substantial equivalence is claimed:  
Sight-Plus Arthroscope K925226**

**Intended Use: This device is intended to provide access, illumination and  
allow observation or manipulation of body cavities, hollow  
organs, and canals.**

**Description: This device has an overall length of 354mm. This diameter of the  
shaft is 2.7mm for direction of the center of field of view of 0/30/70  
degrees. Diameter of the shaft of 4mm for direction of the center  
of field of view of 0/15/30/70 degrees. This device is composed of  
identical materials to that of the Sight-Plus Arthroscope.**

**"This summary of 510(k) safety and effectiveness information is being submitted  
in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."**