



Food and Drug Administration  
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February 12, 2016

Arthrex Incorporated  
Mr. David Rogers  
Regulatory Affairs Specialist  
1370 Creekside Boulevard  
Naples, Ohio 34108

Re: K153218  
Trade/Device Name: Arthrex Synergy UHD4 System  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: Class II  
Product Code: GCJ  
Dated: January 14, 2016  
Received: January 15, 2016

Dear Mr. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Jennifer R. Stevenson -S**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K153218

Device Name

Arthrex Synergy UHD4 System

Indications for Use (Describe)

The Arthrex Synergy UHD4 System is intended to be used as an endoscopic video camera in a variety of endoscopic surgical procedures, including but not limited to: orthopedic, laparoscopic, urologic, sinusopic, and plastic surgical procedures. The device is also intended to be used as an accessory for microscopic surgery.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510K SUMMARY OF SAFETY AND EFFECTIVENESS

<b>Date Summary Prepared</b>	October 22, 2015
<b>Manufacturer/ Distributor/ Sponsor</b>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
<b>510(k) Contact</b>	David L Rogers Regulatory Affairs Specialist Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 71924 Fax: 239/598.5508 Email: david.rogers@Arthrex.com
<b>Trade Name</b>	<b>Arthrex Synergy<sup>UHD4</sup> System</b>
<b>Common Name</b>	Endoscopic Video Camera System
<b>Product Code, Classification Name, CFR</b>	<b>G CJ</b> <b>21 CFR 876.1500: Endoscope and accessories</b>
<b>Predicate Device</b>	K071756: Endohub-1.0 Endoscopic Video Camera with Video Capture
<b>Purpose of Submission</b>	This Special 510(k) premarket notification is intended to address modifications to the Endohub-1.0 Endoscopic Video Camera with Video Capture cleared under predicate K071756.
<b>Device Description</b>	The <b>Arthrex Synergy<sup>UHD4</sup> System</b> consists of a camera head with light source and a Camera Control Unit (CCU). The system is used in conjunction with an endoscope to allow for visualization onto a monitor during minimally invasive surgical procedures.
<b>Indications for Use</b>	The <b>Arthrex Synergy<sup>UHD4</sup> System</b> is intended to be used as an endoscopic video camera in a variety of endoscopic surgical procedures, including but not limited to: orthopedic, laparoscopic, urologic, sinusoscopic, and plastic surgical procedures. The device is also intended to be used as an accessory for microscopic surgery.
<b>Substantial Equivalence Summary</b>	<p>The <b>Arthrex Synergy<sup>UHD4</sup> System</b> is substantially equivalent to the predicate device in which the basic design features and intended uses are the same. Any differences between the <b>Arthrex Synergy<sup>UHD4</sup> System</b> and the predicates are considered minor and do not raise questions concerning safety and effectiveness.</p> <p>There are no significant differences between the new device and predicate that raise issues of safety or effectiveness. Bench testing was performed to demonstrate equivalence to the predicate regarding environmental conditions, power requirements, image capture, and video output and resolution. Sterilization and electrical safety validations were performed on the system components and comply with ISO 17665-1 and IEC 60601-1:2012 3<sup>rd</sup> Edition. Accordingly, Arthrex believes that the Arthrex Synergy<sup>UHD4</sup> System is substantially equivalent to the Endohub-1.0 Video Camera System cleared under K071756.</p> <p>Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the <b>Arthrex Synergy<sup>UHD4</sup> System</b> are substantially equivalent to the predicate.</p>

## MANUFACTURER / SPONSOR / CONTACT

### 1.1.1.1 MANUFACTURER / SPONSOR

Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, Florida 34108-1945 USA  
Establishment Registration Number: 1220246

### 1.1.1.2 CONTACT

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