DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 8, 2014

BioVision Technologies, LLC
Mr. David Sanso
President
221 Corporate Circle, Unit H
Golden, Colorado 80401

Re: K141326
Trade/Device Name: NeedleView CH™ Scope Kits
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, GCJ
Dated: August 22, 2014
Received: September 2, 2014

Dear Mr. Sanso:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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" (21CFR 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,

Binita S. Ashar -S
2014.10.08 12:36:21 -04'00'

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

INDICATIONS FOR USE

510(k) Number (if known): K141326

Device Name: NeedleView CH™ Scope Kits

Indications for Use: This system is indicated to be used by a trained physician to provide illumination and visualization of an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures. Examples of surgical use include but are not limited to procedures on the knee, shoulder, ankle, elbow, wrist, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and the cervix.

Prescription Use X	AND/OR	Over-The-Counter Use N/A
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

NeedleView CH™ Scope Kits
Traditional 510(k) Submission

510(k) SUMMARY

Submission Information

Date:	October 7, 2014
Applicant:	BioVision Technologies, LLC.
Address:	221 Corporate Circle Unit H Golden, Colorado 80401
Telephone Number:	303-237-9608
Submitter's Contact:	David Sanso, President

Device Information

Proprietary Name:	**NeedleView CH Scope Kit**
Regulation Number:	**21 CFR 888.1100**
Regulation Name:	**Arthroscope / Endoscope**
Regulatory Class:	**II**
Product Codes(s):	**HRX, GCJ**

Predicate Devices

BioVision SurgView™ Integrated Visualization System (K082293)
Joimax THESSYS Multiscope (K051827)
Hoogland Spine Products maxMorespine Endoscope (K083552)
Blazejewski MEDI-Tech Spinal Foraminoscope (K082841)
Richard Wolf Medical Instruments Corp. Endoscopic Spine System Set (YESS) (K973405)

Device Description

Name of Device: NeedleView CH™ Scope Kit

The NeedleView CH is a rigid Fiberoptic scope with a working channel designed for single use. The product consists of a 17,000 pixel coherent silica fiber bundle, 30μm diameter light fibers and a stainless steel channel encased in a stainless steel shaft. The effective field of view is 80° in air and 62° in water. The direction of view is 0°. The scope has retaining groves to incorporate a drape that will cover the camera and cord that connects to the SurgView System. The NeedleView CH Scope Kit consists of a fiber-optic based micro-endoscope (3.4mm Outer Diameter, 1.85mm Working Channel, 160mm Working Length), 12F Cannula (4mm Inner Diameter), 12F Dilator(4mm Diameter), 14Gx127mm Tuohy Needle, 18Gx152mm Tuohy

Needle, #11 Scalpel, Guidewire (70cm Length), Hemostasis Valve Adapter (HVA), and a sterile drape. All of these items are disposable and for single-use only. The micro-endoscope is made to couple with a non-disposable system hand piece that contains a light source and camera, which is available separately.

Statement of Intended Use

The system is indicated to be used by a trained physician to provide illumination and visualization of an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures. Examples of surgical use include but are not limited to procedures on the knee, shoulder, ankle, elbow, wrist, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and the cervix.

Comparison to Predicate Devices

Table 1: The table below shows relevant similarities and difference between the NeedleView CH and its predicate devices.

Feature	BioVision SurgView™ Integrated Visualization System	Joimax THESSYS Multiscope	Hoogland Spine Products msxMorespine Endoscope & System	Blazejewski MEDI-Tech Spinal Foraminoscope	Richard Wolf Medical Instruments Corp. Endoscopic Spine System Set (YESS)
Similarities					
Intended Use	X	X	X	X	X
Scope Shaft Material	X	X	X		X
Labeling (Single Use/Reusable)	X				
Differences					
Labeling (Single Use/Resuable)		X	X	X	X
Outer Diameter	X			X	
Number of Channels		X		X	X

Summary of Technologies

The technological characteristics of the BioVision NeedleView CH are similar to those of the predicate devices listed.

Performance Testing

The following performance tests were completed on the BioVision NeedleView CH Kit.

NeedleView CH Scope Performance Testing
- NeedleView CH Performance Testing
- NeedleView CH Accelerated Aging Performance Testing

Tuohy Needle Performance Testing
- Flexural Test for 14G Tuohy Needle
- Flexural Test for 18G Tuohy Needle
- 18G Tuohy Needle Buckling Test
- Tuohy Needle Puncture Test Summary

Cannula Performance Testing
- Cannula Insertion and Withdrawal Test including the 12F dilator
- Cannula Leak Test
- Cannula Bending Test
- Cannula Crushing Test
- Cannula Tensile Test

HVA
- HVA Fit and Leak Test

Guidewire Test
- Guidewire Tensile Test
- Guidewire Compression Test
- Guidewire Flexural Test

Biocompatibility testing was completed utilizing the following standard:
- ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

Packaging, sterilization, distribution and accelerated aging testing were completed utilizing the following standards:
- ISO 11607-2:2006 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming , sealing and assembly processes
- ASTM F2096:2011, Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)
- ASTM F88:2009, Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1886:2009, Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection
- ANSI/AAMI/ISO 11135:2007 – Part 1, Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

- EN 556:2006, Sterilization of medical devices – Requirements for terminally-sterilized medical devices to be labeled "Sterile"
- AAMI TIR28:2009, Product adoption and process equivalency for ethylene oxide sterilization
- ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
- ANSI/AAMI/ISO 11135-2:2008, Guidance on the application of 11135-1
- ISO 11737-1:2006, Determination of a population of microorganisms on products
- ISO 11137-3:2004, Guidance on evaluation and interpretation of bioburden data
- ISTA 2A:2011, Partial-Simulation Performance Test Procedure: Packaged-Products 150lb (68 kg) or Less
- ASTM D4169:2009, Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F 1980:2007, Guide to Accelerated Aging of Sterile Medical Device Packages

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Clinical Testing

Clinical testing was not used to prove substantial equivalence. Establishment of equivalence is based on similarities of intended use, design, physical characteristics and geometry between the BioVision NeedleView CH and predicate devices.

Conclusion

Based on the evaluation of the performance characteristics, construction, manufacturing processes, and indications of use, BioVision Technologies has concluded that the BioVision NeedleView CH is substantially equivalent to the predicate devices listed. In all cases, the characteristics of this device are identical or similar to the predicate devices as they relate to the intended uses or application. The indications and contraindications of this device and those of the predicates listed in this submission are in congruence between devices. BioVision Technologies has also determined that the differences in characteristics indicated in this evaluation do not adversely affect the safety and effectiveness of the BioVision NeedleView CH.