Records processed under FOIA Request #2015-10065; Released by CDRH on 09-26-2016.

BIO VISION Technologies, LLC
Visualizing Better Care

221 Corporate Circle, Suite H
Golden, Colorado 80401 USA
Phone: 303-237-9608 • Fax: 303-237-0757
www.biovisiontech.com

K143705

SPECIAL 510(K) NOTIFICATION Cover Letter

FDA CDRH DMC
DEC 31 2014
Received

Date:	**December 30, 2014**
Applicant:	BioVision Technologies, L.L.C.
Address:	221 Corporate Circle Unit H Golden, Colorado 80401
Contact Person:	David Sanso President (303) 237-9608
Type of Submission:	**Special 510(K)**
Propriety Name:	NeedleCam HD™ Visualization System
Regulation Name:	Arthroscope/Endoscope
Classification Regulation:	21 CFR §888.1100, 21 CFR 876.1500
Classification Name:	Arthroscope / Endoscope and Accessories
Regulatory Class:	II
Prior Submissions:	There have been no prior submissions for this device
Continued Confidentiality:	BioVision Technologies agrees to the confidentiality agreement outlined in 21 CFR §807.95.
FDA Panel:	87 / 78
Product Code:	HRX/GCJ

Purpose: The purpose of this Special 510(k) submission is to request a modification for our BioVision Technologies SurgView™ Integrated Visualization System that has been granted marketing clearance by FDA under the number **K082293** on the 9th of September, 2008. The modification is an incremental change of an existing device that does not affect safety and effectiveness of the device.

The current system consists of an Image Capture Box, Camera Handpiece and endoscopes. The modification is to update the image capture box to the current standard USB storage device, to

1-CD
87

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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update the existing video format to the current digital format. The camera handpiece has also been upgraded with an LED light source. There has been no change in design, packaging or sterilization of the endoscopes used with the current system.

The upgrades were completed to incorporate the improved light source options provided by LED lighting. The industry standard for media storage has moved from CF cards to USB technology. Additionally, analog television technology has been replaced by digital television technology. It should be also noted that we submit the Special 510(k) under a different name than the equivalent device we refer to. The Trade name of our modified device is NeedleCam HD™. Visualization System.

We believe these modifications are eligible for the Special 510 (k) process since they do not change the intended use and do not alter the fundamental scientific technology of the device.

Predicate Device:

BioVision Technologies, LLC **SurgView™ Integrated Visualization System** **K082293**

Device and Use of the Device

Question	YES / NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	Yes
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	No
Does the device contain components derived from a tissue or other biologic source?	No
Is the device provided sterile?	No (The scopes used with the system are provided sterile – there is no change to the scopes.)
Is the device intended for single use?	No (The scopes used with the system are single use – there is no change to the scopes)
Is the device a reprocessed single use device? (If yes, does this device type require reprocessed validation data?)	No
Des the device contain a drug?	No
Does the device contain a biologic?	No
Does the device use software?	Yes
Does the submission include clinical information?	No
Is the device implanted?	No

eCopy Statement: The eCopy is an exact duplicate of the paper copy.

Submitters Signature:

David Sanso, President

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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FDA CDRH DMC
DEC 29 2014
Received

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Address:	221 Corporate Circle Unit H Golden, Colorado 80401
Contact Person:	David Sanso President (303) 237-9608
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Propriety Name:	NeedleCam HD™ Visualization System
Regulation Name:	Arthroscope/Endoscope
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Product Code:	HRX/GCJ

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Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

BIOVISION TECHNOLOGIES LLC
221 CORPORATE CIRCLE UNIT H
GOLDEN
CO 80401
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****0915

2. CONTACT NAME
David Sanso

2.1 E-MAIL ADDRESS
dsanso@biovisiontech.com

2.2 TELEPHONE NUMBER (include Area code)
303-237-9608 102

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
303-237-0757

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EDISTATUS@fda.hhs.gov or call 301-796-8048.

Records processed under FOIA Request #2015-10065; Released by CDRH on 09-26-2016.

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4) [redacted] 22-Dec-2014

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Records processed under FOIA Request #2015-10065; Released by CDRH on 09-26-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
12/23/2014	(b) (4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☒ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
BioVision Technologies, LLC	3004452289		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	303-237-9608		
Street Address	**FAX Number *(including area code)***		
221 Corporate Circle, Unit H	303-237-0757		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Golden	CO	80401	USA
Contact Name			
David Sanso			
Contact Title	**Contact E-mail Address**		
President	dsanso@biovisiontech.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

PSC Publishing Services (301) 443-6740 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify)*:

A Change to an Existing Device (K082293)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-10065; Released by CDRH on 09-26-2016.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	K082293	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K082293	1	SurgView Integrated Visualization System	1	BioVison Technologies, LLC
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Arthroscope, Endoscope

	Trade or Proprietary or Model Name for This Device		Model Number
1	NeedleCam HD Visualization System	1	BVT01197-00001, BMT01197-00001, LUT01197-00001
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
HRX/GCJ	21CFR	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

888.1100 - Arthroscope; 876.1500- Endoscope and accessories

Indications *(from labeling)*

The NeedleCam HD 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.

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Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 3004452289	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: BioVision Technologies, L.L.C.		Establishment Registration Number: 3004452289	
Division Name *(if applicable)*: n/a		Phone Number *(including area code)*: 303-237-9608	
Street Address: 221 Corporate Circle, Unit H		FAX Number *(including area code)*: 303-237-0757	
City: Golden	State / Province: CO	ZIP Code: 80401	Country: USA
Contact Name: David Sanso	Contact Title: President	Contact E-mail Address: dsanso@bivisiontech.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
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City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H *(Continued)*

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
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SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	ANSI/AAMI ES	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	3d Edition	01/01/2005
2	60601-2-18	IEC	Amendment 1, Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment	3.0	08/01/2009
3	60601-1-2	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	3rd Edition	March 2007
4	62304	IEC	Medical Device Software - Software Life Cycle Processes	1.0	May 2006
5					
6					
7					

Please include any additional standards to be cited on a separate page.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Phone: 303-237-9608 • Fax: 303-237-0757
www.biovisiontech.com

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update the existing video format to the current digital format. The camera handpiece has also been upgraded with an LED light source. There has been no change in design, packaging or sterilization of the endoscopes used with the current system.

The upgrades were completed to incorporate the improved light source options provided by LED lighting. The industry standard for media storage has moved from CF cards to USB technology. Additionally, analog television technology has been replaced by digital television technology. It should be also noted that we submit the Special 510(k) under a different name than the equivalent device we refer to. The Trade name of our modified device is NeedleCam HD™. Visualization System.

We believe these modifications are eligible for the Special 510 (k) process since they do not change the intended use and do not alter the fundamental scientific technology of the device.

Predicate Device:

BioVision Technologies, LLC **SurgView™ Integrated Visualization System** **K082293**

Device and Use of the Device

Question	**YES / NO**
Is the device intended for prescription use (21 CFR 801 Subpart D)?	Yes
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	No
Does the device contain components derived from a tissue or other biologic source?	No
Is the device provided sterile?	No (The scopes used with the system are provided sterile – there is no change to the scopes.)
Is the device intended for single use?	No (The scopes used with the system are single use – there is no change to the scopes)
Is the device a reprocessed single use device? (If yes, does this device type require reprocessed validation data?)	No
Des the device contain a drug?	No
Does the device contain a biologic?	No
Does the device use software?	Yes
Does the submission include clinical information?	No
Is the device implanted?	No

eCopy Statement: The eCopy is an exact duplicate of the paper copy.

Submitters Signature:

David Sanso, President

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Acceptance Checklist
for Special 510(k)s

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) Number: _____ **Date Received by DCC:** _____

Lead Reviewer Name: _____ **Branch:** _____ **Division:** _____ **Office:** _____

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during RTA and that element will be assessed during substantive review.

Special 510(k) Criteria **The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.**		
	Yes	**No**
1. 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	✓	
Comments:		
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	✓	
Comments:		
3. Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	✓	
Comments:		
4. The submission includes only summary-level information (i.e., NO test reports with performance data). *Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.*	✓	
Comments:		

Does the submission meet all 4 criteria above?

☑ Yes, submission meets criteria for a Special 510(k). Continue with the remainder of this checklist below.

☐ No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist; convert to a Traditional and apply the Traditional checklist.

Acceptance Checklist for Special 510(k)

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Organizational Elements *Failure to include these items along generally should not result in an RTA designation*		
	Yes	**No**
a. Submission contains Table of Contents	☑	☐
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☑	☐
c. All pages of the submission are numbered *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).*	☑	☐
d. Type of 510(k) is identified– traditional, abbreviated, or special *If type of 510(k) is not designated, review as a traditional*	☑	☐
Comments:		

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)		☑		☐
		Comments:				
	2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or in 510(k) cover letter):		☑		☐
		a.	Device trade name or proprietary name	☑		☐
		b.	Device common name	☑		☐
		c.	Device class and panel or Classification regulation or	☑		☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			Statement that device has not been classified with rationale for that conclusion		✓	
		Comments:				
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also and 801.109) *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.*		☑		☐
		Comments:				
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.*		☑		☐
		a.	Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	☑	☐	☐
		b.	Statement contains all elements per 21 CFR 807.93	☐		☐
		Comments:				
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format. Select "Yes" if statement is present, and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).*		☑		☐
		Comments:				
	6.	Submission contains Class III Summary and Certification *See recommended content* *Form should be signed by a responsible person of the firm, not a*		☐	☑	☐

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				Yes	N/A	No
Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		consultant. Select "N/A" only if submission is not a Class III 510(k).				
		Comments:				
	7.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed. *There should be a completed form for each referenced national or international standard.* *Select "N/A" only if submission does not reference any standards.*		☑	☐	☐
		Comments:				
	8.	The submission identifies prior submissions for the same device which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device. *This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions). Alternatively, a list of submission numbers may be found in Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions.*		☑		☐
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed.	☐	✓	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			To address this criterion, the submission may include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm). Once finalized, this guidance will represent the Agency's current thinking on this topic. *Select "N/A" if the submitter states there were no prior submissions in criterion above.*		☑	
		Comments: No prior submission for this device.				
B.	**Device Description**					
	9.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☐	☑	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the	☐	☑	☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*			
		Comments:				
	10.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	☑		☐
		b.	A description of proposed conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☑		☐
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, or various sizes, etc.*	☑	☐	☐
		Comments:				
	11.	A description of all device modification(s) including rationale for each modification.		☑		☐
		Comments:				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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				Yes	N/A	No
Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. *In lieu of drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.* *Select "N/A" if the sponsor provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).*		☑	☐	☐
		Comments:				
	13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.*		✓	☐	
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☑		☐
		b.	Submission includes a description (as detailed in item #12.a. and b. and 14 above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☑	☐	☐
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/accessory(ies) does not have a prior 510(k) clearance or the components/accessory(ies) is 510(k) exempt.*	☑	☐	☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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				Yes	N/A	No
Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		Comments:				
C.	**Substantial Equivalence Discussion**					
	14.	Submitter has identified a predicate(s) device		☑		☐
		a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm).*	☑		☐
		b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☑		☐
		Comments:				
	15.	Submission includes a comparison of the following for the predicate(s) and subject device				
		a.	Indications for use	☑		☐
		b.	Technology, including features, materials, and principles of operation	☑		☐
		Comments:				
	16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, and any differences in technological characteristics are accompanied by information that demonstrates the		☑		☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed							
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**
		device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate) affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(l)(A) of the FD&C Act) *If there is no difference between the subject and predicate(s with respect to the indications or technology), this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis should be assessed during the substantive review; only the presence of such an analysis is required for acceptance.*					
		Comments:					
D.	**Design Control Activities**						
	17.	Design Control Activities Summary includes all of the following:					
		a.	Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis		☑		☐
		b.	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.		☑		☐
		c.	Declaration of conformity with design controls, including: *All 3 must be present to answer "Yes."*		☑		☐
			i.	Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met.			
			ii.	Statement that manufacturing facility is in conformance with design control			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**
				procedure requirements as specified in 21 CFR 820.30			
			iii.	Statement is signed by the individual responsible for these activities			
	Comments:						
E.	**Proposed Labeling (see also 21 CFR part 801)**						
	18.	Submission includes proposed package labels, and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use			☑		☐
		a.	All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.		☑		☐
	Comments:						
	19.	Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).			☑		☐
	Comments:						

Decision: Accept ___ Refuse to Accept ___

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Reviewer Signature: _____ **Date:** _____

Supervisory Signature: _____ **Date:** _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
NeedleCam HD™ Visualization System

Indications for Use *(Describe)*
NeedleCam HD™ Visualization System

Indications for Use: The NeedleCam HD™ Visualization 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.

This is the same intended use as for a previously cleared device - the BioVision Technologies SurgView™ Integrated Visualization System (K082293).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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BIO VISION Technologies, LLC
Visualizing Better Care

221 Corporate Circle, Suite H
Golden, Colorado 80401 USA
Phone: 303-237-9608 • Fax: 303-237-0757
www.biovisiontech.com

Needle Cam HD™ Visualization System
Special 510(k) Submission

SPECIAL 510(k) SUMMARY

Submission Information

Date Prepared: December 22, 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: NeedleCam HD™ Visualization System

Common Name: Arthroscope/Endoscope

Classification Name: Arthroscope / Endoscope and Accessories

Regulation Number: 21 CFR §888.1100, HRX

21 CFR §876.1500, GCJ

Regulatory Class: II

Predicate Device

BioVision Technologies SurgView™ Integrated Visualization System (K082293)

Device Description

Name of the Device: NeedleCam HD™ Visualization System

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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NeedleCam HD™ Visualization System is comprised of an Image Capture Box, a Camera Handpiece (including an LED light source) that captures still images and full resolution video, and External Power Supply. The camera has a quick-release optical connector that adapts to a wide variety of Bio Vision Technologies' surgical endoscopes. The device is used with an endoscope to visualize and illuminate an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures.

The BioVision endoscopes and supplemental instruments that were approved with the predicate SurgView Visualization System have not been changed.

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.

NeedleCam HD System Components and Accessories

The NeedleCam HD Visualization System is intended to be used with BioVision endoscopes. The following is a listing of the current compatible scopes, along with the applicable 510(k) clearance numbers.

Part Number	Description	510(k) Number
BVTKIT72-0L065	OnPoint 0 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-0L165	BioVision NeedleView 0 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-0L1A0	BioVision NeedleView 0 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R165	BioVision NeedleView 10 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R1A0	BioVision NeedleView 10 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R265	InnerVue II 10 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R2A0	InnerVue II 10 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293

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BVTKIT75-3R165	BioVision NeedleView 30 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT75-3R1A0	BioVision NeedleView 30 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT82-34001	BioVision NeedleView CH 3.4mm Scope Kit (including scope, cannula, dilator, tuohy needles, scalpel and guidewire	K141326

Comparison to Predicate Device

The table below shows relevant similarities and differences between the NeedleCam HD™ Visualization System and its predicate device – SurgView™ Integrated Visualization System (K082293).

APPLICANT DEVICE: NeedleCam HD™ Visualization System

PREDICATE DEVICE: SurgView™ Visualization System (K082293)

NOTE: **Relevant similarities are identified in bold text.**
Relevant differences are identified in underlined text.

PREDICATE COMPARISON CHART

I. GENERAL CHARACTERISTICS			PREDICATE DEVICE
ITEM	**FEATURE**	**NeedleCam HD Visualization System**	**SurgView™ Visualization System K082293**
1	**Device Description**	NeedleCam HD Visualization System **is a video endoscope/arthroscope imaging system consisting of the following components:** 1. **An Image Capture Box that includes image processor and** external power supply) 2. **Camera handpiece** including a LED light source. 3. **A semi-rigid Fiberoptic Scope in a variety of diameters, lengths, and viewing angles. Supplemental instruments include a cannula, trocar, obturator, and cannula plug.** 4. Media Capture USB System 5. **Video Outputs for external monitor**	The SurgView™ Visualization System **is a video endoscope/arthroscope imaging system consisting of the following components:** 1. **A Light Source/Display/Image Capture device that includes** an internal monitor, **image processor,** Xenon light source and internal power supply**.** 2. **Camera handpiece**. 3. **A semi-rigid Fiberoptic Scope in a variety of diameters, lengths, and viewing angles. Supplemental instruments for the scope include a cannula, trocar, obturator, and cannula plug.** 4. Media Capture CF Card System 5. **Video output for external monitor.**

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2	Intended Use	Needle Cam HD™ **Visualization 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, shoulder, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and cervix**.	The SurgView™ **Visualization 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, shoulder, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and cervix**.
3	Materials Used	**Plastic enclosure, media capture board**, **plastic camera cable.** **Scopes & instruments - Stainless Steel for Scope Shaft; Fiber Optics for light transmission**	**Plastic enclosure,** metal plate, **media capture board**, **plastic camera cable**, and fiber optic cable**.** **Scopes & instruments - Stainless Steel for Scope Shaft; Fiber Optics for light transmission**
4	Labeling (Single Use/Reusable)	**Image capture box and camera handpiece: Reusable.** **Scopes & instruments: Sterile, Single Use**	**Image capture box and camera handpiece: Reusable.** **Scopes & instruments: Sterile, Single Use**
5	Image acquisition	**Image acquisition is achieved through an endoscope attached to a camera handpiece. The endoscope is in the sterile field while the handpiece remains non-sterile. A barrier is provided to preserve the sterile field.**	**Image acquisition is achieved through an endoscope attached to a camera handpiece. The endoscope is in the sterile field while the handpiece remains non-sterile. A barrier is provided to preserve the sterile field.**
6	Connectivity	**The endoscope, camera handpiece, cable, illumination source and image processor connections allow functional coupling of the components while providing safe and reliable connections, in particular those related to electrical safety for the user and patient. The endoscope attached to the camera handpiece using a quick release connection.** The LED light source is included in the camera handpiece. **The camera cable connects to the image capture device using a single electrical connector.**	**The endoscope, camera handpiece, cable, illumination source and image processor connections allow functional coupling of the components while providing safe and reliable connections, in particular those related to electrical safety for the user and patient. The endoscope attached to the camera handpiece using a quick release connection.** The fiberoptic bundle is integrated with the camera cable. **The camera cable connects to the** light source**/image capture device using a single hybrid (electrical/optical) connector.**
7	Image processing	**The image is digitally processed to allow further manipulation, capture, printing, and multiple displays.**	**The image is digitally processed to allow further manipulation, capture, printing, and multiple displays.**
8	Image display (s)	**External monitor connection**	Internal monitor display with **external monitor connection.**
9	Data Entry	**Session information entered via external keyboard**	**Session information entered via external keyboard**

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10	Data storage	Image and video storage to USB device	Image and video storage to Compact Flash™ cards.
11	Where used	**Hospital / Doctor's office**	**Hospital / Doctor's office**
II. CHARACTERISTICS OF THE LIGHT SOURCE			
ITEM	FEATURE	**NeedleCam HD™ Visualization System**	**SurgView™ Visualization System K082293**
1	Illumination	**Illumination is achieved via** an internal LED light source. **The** LED **light source is an integral part of the device.** The LED is internal to the camera handpiece. **LED and Xenon usable light output is equivalent.**	**Illumination is achieved via** a fiberoptic bundle attached to the endoscope**. The** Xenon **light source is an integral part of the device.** The Xenon light source is internal to the image capture box. **LED and Xenon usable light output is equivalent.**
2	Type of light source	LED	Xenon
3	Lamp power rating	1W	35W
4	Rated lamp life	20,000 hours	3,000 hours
5	Luminous intensity as measured at scope output	**4-6 lumens**	**4-6 lumens**
III. CHARACTERISTICS OF THE CAMERA			
ITEM	FEATURE	**NeedleCam HD™ Visualization System**	**SurgView™ Visualization System**
1	Camera sensor	**¼" CCD**	**¼" CCD**
2	Sensor resolution	**768(H) x 494(V) pixels**	**768(H) x 494(V) pixels**
3	Camera resolution	**480 lines, interlaced**	**480 lines, interlaced**
4	Camera sterility	**Non sterile. Drape is used for sterile field preservation.**	**Non sterile. Drape is used for sterile field preservation.**
5	Endoscope coupler	**Built-in**	**Built-in**

Conclusion: Based on the evaluation of the performance characteristics, construction, manufacturing processes, and indications of use, BioVision Technologies has concluded that the BioVision NeedleCam HD ™ Visualization System is substantially equivalent to the predicate device listed in this submission.

The upgrades were completed to incorporate the improved light source options provided by LED lighting. The industry standard for media storage has moved from CF cards to USB technology. Additionally, analog television technology has been replaced by digital television technology.

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Summary of Technologies

The technological characteristics of the BioVision NeedleCam HD™ Visualization System are similar to its predicate device – BioVision SurgView™ Visualization System (K082293). The indications and contraindications listed in this submission are in congruence between these devices. The modifications are incremental changes to the predicate image capture box and camera handpiece that do not affect safety and effectiveness of the modified device. The modifications are the following:

1) Update the image capture box to the current standard USB storage device;
2) Update the existing video format to the current digital format.
3) The camera handpiece has been upgraded with an LED light source.

We believe these modifications are eligible for the Special 510 (k) process since they have the same fundamental scientific technology and intended use as the predicate device.

Performance Testing

Establishment of equivalence is based on similarities of intended use, design, physical characteristics and geometry between the BioVision NeedleCam HD™ Visualization System and its predicate device – BioVision SurgView™ Visualization System (K082293).

Safety testing was completed to ANSI/AAMI ES 60601-1:2005 (3rd edition) on the BioVision NeedleCam HD™ Visualization System. Additionally software validation was completed on the system.

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 Needle Cam HD and its predicate device.

Conclusion

Based on the evaluation of the performance characteristics, construction, manufacturing processes, and indications of use, BioVision Technologies has concluded that the BioVision Needle Cam HD™ Visualization System is substantially equivalent to the predicate device listed above. In all cases, the characteristics of this device are identical or similar to the predicate device as they relate to the intended uses or application. BioVision Technologies has also determined that the modification is an incremental change to the existing device that does not affect safety and effectiveness of the device.

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI ES60601-1

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#19-5	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI ES60601-1

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#19-1	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1-2

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-2-18

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Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#4-187	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-2-18

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62304

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#13-8	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: General Principles of Software Validation: Final Guidance for Industry and FDA Staff, 11-Jan-2002

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 62304

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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

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PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as President of BioVision Technologies, LLC. I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



(Signature)

David Sanso

(Typed Name)

December 22, 2014 .

(Date)

(Premark Notification [510(k)] Number)

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Legally Marketed Unmodified Device

SurgView™ Integrated Visualization System (K082293)

DEVICE IDENTIFICATION

Proprietary Name: SurgView™ Integrated Visualization System

Regulation Name: Arthroscope/ Endoscope

510(k) Number: K082293

Regulation Number: 21 CFR §888.1100, HRX
21 CFR §876.1500, GCJ

Regulatory Class: II

SurgView™ Integrated Visualization System (K082293) is the referenced 510(k) device and was submitted to the FDA by BioVision Technologies.

BioVision Technologies is submitting the Special 510(k) under a different Trade name. The Trade name of our modified device is NeedleCam HD™ Visualization System.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Golden, Colorado 80401 USA
Phone: 303-237-9608 • Fax: 303-237-0757
www.biovisiontech.com

NeedleCam HD™ Visualization System
Special 510(k) Submission

DESCRIPTION OF THE MODIFIED DEVICE
BioVision NeedleCam HD™ Visualization System

A. ADMINISTRATIVE INFORMATION

Applicant:	BioVision Technologies, LLC.
Address:	221 Corporate Circle, Suite H Golden, Colorado 80401
Telephone Number:	(303) 237-9608
Facsimile Number:	(303) 237-0757
Contact Person:	David Sanso President

Manufacturing Site(s):

Design Holder:

BioVision Technologies, LLC.
221 Corporate Circle, Suite H
Golden, Colorado 80401
Establishment Registration Number: 3004452289

B. DEVICE IDENTIFICATION

Proprietary Name:	NeedleCam HD™ Visualization System
Classification Name:	Arthroscope/Endoscope
Regulation Number:	21 CFR §888.1100, 21 CFR 876.1500
Regulatory Class:	II
FDA Panel:	87 / 78
Product Code:	HRX/GCJ

Device Description
Name of the Device: NeedleCam HD™ Visualization System

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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NeedleCam HD™ Visualization System is comprised of an Image Capture Box with connections to an external monitor, a Camera Handpiece (including an LED light source) that captures still images and full resolution video, and an External Power Supply. The camera has a quick-release optical connector that adapts to a wide variety of Bio Vision Technologies' surgical endoscopes. The device is used with an endoscope to visualize and illuminate an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures.

The BioVision endoscopes and supplemental instruments that were approved with the predicate SurgView Visualization System have not been changed.

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 Device

The table below shows relevant similarities and difference between the NeedleCam HD™ Visualization System and its predicate device- SurgView™ Integrated Visualization System (K082293).

APPLICANT DEVICE: NeedleCam HD™ Visualization System
PREDICATE DEVICE: SurgView™ Visualization System (K082293)
NOTE: **Relevant similarities are identified in bold text.**
Relevant differences are identified in underlined text.

PREDICATE COMPARISON CHART

I. GENERAL CHARACTERISTICS			PREDICATE DEVICE
ITEM	**FEATURE**	**NeedleCam HD Visualization System**	**SurgView™ Visualization System K082293**
1	**Device Description**	NeedleCam HD Visualization System **is a video endoscope/arthroscope imaging system consisting of the following components:** 1. **An Image Capture Box that includes image processor and** external power supply. 2. **Camera handpiece** including an LED light source.	The SurgView™ Visualization System **is a video endoscope/arthroscope imaging system consisting of the following components:** 1. **A Light Source/Display/Image Capture device that includes** an internal monitor, **image processor,** Xenon light source and internal power supply**.** 2. **Camera handpiece**.

		3. **A semi-rigid Fiberoptic Scope in a variety of diameters, lengths, and viewing angles. Supplemental instruments include a cannula, trocar, obturator, and cannula plug.** 4. Media Capture USB System 5. **Video Outputs for external monitor**	3. **A semi-rigid Fiberoptic Scope in a variety of diameters, lengths, and viewing angles. Supplemental instruments for the scope include a cannula, trocar, obturator, and cannula plug.** 4. Media Capture CF Card System 5. **Video output for external monitor.**
2	Intended Use	Needle Cam HD™ **Visualization 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, shoulder, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and cervix**.	The SurgView™ **Visualization 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, shoulder, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and cervix**.
3	Materials Used	**Plastic enclosure, media capture board**, **plastic camera cable.** **Scopes & instruments - Stainless Steel for Scope Shaft; Fiber Optics for light transmission**	**Plastic enclosure,** metal chassis, **media capture board**, **plastic camera cable,** and fiber optic cable. **Scopes & instruments - Stainless Steel for Scope Shaft; Fiber Optics for light transmission**
4	Labeling (Single Use/Reusable)	**Image capture box and camera handpiece: Reusable.** **Scopes & instruments: Sterile, Single Use**	**Image capture box and camera handpiece: Reusable.** **Scopes & instruments: Sterile, Single Use**
5	Image acquisition	**Image acquisition is achieved through an endoscope attached to a camera handpiece. The endoscope is in the sterile field while the handpiece remains non-sterile. A barrier is provided to preserve the sterile field.**	**Image acquisition is achieved through an endoscope attached to a camera handpiece. The endoscope is in the sterile field while the handpiece remains non-sterile. A barrier is provided to preserve the sterile field.**
6	Connectivity	**The endoscope, camera handpiece, cable, illumination source and image processor connections allow functional coupling of the components while providing safe and reliable connections, in particular those related to electrical safety for the user and patient. The endoscope attached to the camera handpiece using a quick release connection.** The LED light source is included in the camera handpiece. **The camera cable connects to the image capture device using a single electrical connector.**	**The endoscope, camera handpiece, cable, illumination source and image processor connections allow functional coupling of the components while providing safe and reliable connections, in particular those related to electrical safety for the user and patient. The endoscope attached to the camera handpiece using a quick release connection.** The fiberoptic bundle is integrated with the camera cable. **The camera cable connects to the** light source**/image capture device using a single hybrid (electrical/optical) connector.**
7	Image processing	**The image is digitally processed to allow further manipulation, capture, printing, and multiple displays.**	**The image is digitally processed to allow further manipulation, capture, printing, and multiple displays.**
8	Image display (s)	**External monitor connection**	Internal monitor display with **external monitor connection.**
9	Data Entry	**Session information entered via external keyboard**	**Session information entered via external keyboard**
10	Data storage	Image and video storage to USB device	Image and video storage to Compact Flash™ cards.
11	Where used	**Hospital / Doctor's office**	**Hospital / Doctor's office**
II. CHARACTERISTICS OF THE LIGHT SOURCE			
ITEM	FEATURE	**NeedleCam HD™ Visualization System**	**SurgView™ Visualization System K082293**
1	Illumination	**Illumination is achieved via** an internal LED light source. **The** LED **light source is an integral part of the device.** The LED is internal to the camera handpiece. **LED and Xenon usable light output is equivalent.**	**Illumination is achieved via** a fiberoptic bundle attached to the endoscope**. The** Xenon **light source is an integral part of the device.** The Xenon light source is internal to the image capture box. **LED and Xenon usable light output is equivalent.**
2	Type of light source	LED	Xenon
3	Lamp power rating	1W	35W
4	Rated lamp life	20,000 hours	3,000 hours

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5	Luminous intensity as measured at scope output	**4-6 lumens**	**4-6 lumens**
III. CHARACTERISTICS OF THE CAMERA			
ITEM	FEATURE	**NeedleCam HD™ Visualization System**	**SurgView™ Visualization System**
1	Camera sensor	**¼" CCD**	**¼" CCD**
2	Sensor resolution	**768(H) x 494(V) pixels**	**768(H) x 494(V) pixels**
3	Camera resolution	**480 lines, interlaced**	**480 lines, interlaced**
4	Camera sterility	**Non sterile. Drape is used for sterile field preservation.**	**Non sterile. Drape is used for sterile field preservation.**
5	Endoscope coupler	**Built-in**	**Built-in**

Conclusion: Based on the evaluation of the performance characteristics, construction, manufacturing processes, and indications of use, BioVision Technologies has concluded that the BioVision NeedleCam HD ™ Visualization System is substantially equivalent to the predicate device listed in this submission. The upgrades were completed to incorporate the improved light source options provided by LED lighting. The industry standard for media storage has moved from Compact Flash (CF) cards to USB technology. Additionally, analog television technology has been replaced by digital television technology.

Drawings:

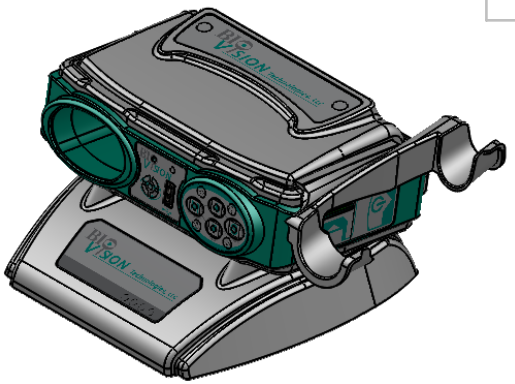
The following drawings provide a view of the modified device.

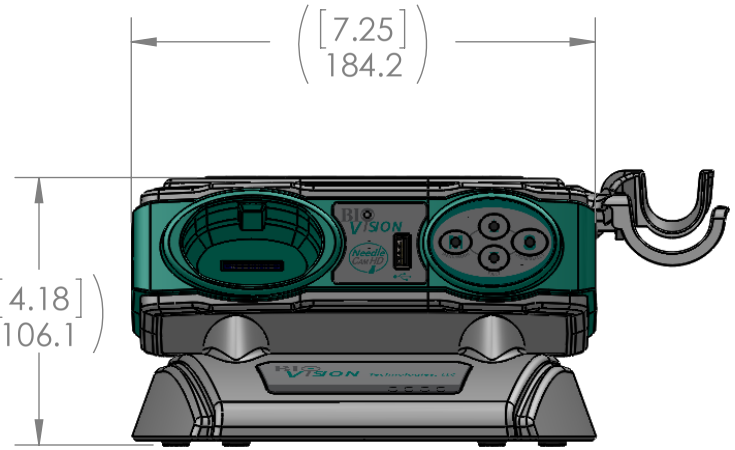
- BVT01097-00001 Image Capture Box Drawing
- BVT01097-03001 Camera Handpiece Drawing

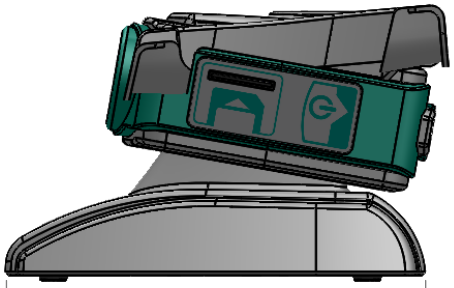
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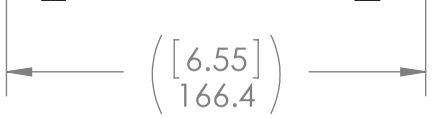
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PART NO:
BVT01097-00001









ECO #	Description	Date	REV.
2539	INITIAL RELEASE	12-18-2014	A

ENGINEERING CHANGE RECORD

UNLESS OTHERWISE SPECIFIED
Dimension are in Millimeters.
TOLERANCES ARE:
DECIMALS: MM ANGLES
.X: +/- .10 +/- 0.5 deg
.XX: +/- .05
DECIMALS: INCHES
.XX: +/- .010
.XXX: +/- .005

MATERIAL
N/A

FINISH
N/A

DO NOT SCALE DRAWING

CAD GENERATED DRAWING,
DO NOT MANUALLY UPDATE

APPROVALS		DATE
MODELED	Pitzer	12-18-2014
DRAWN	Pitzer	12-18-2014
CHECKED	Korte	12-18-2014
RESP ENG	Sanso	12-18-2014
QUAL ENG	Ray	12-18-2014

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303-237-9608, Fax: 303-237-0757

NeedleCam HD
Image Capture Box

SIZE A | DWG. NO. **BVT01097-00001** | REV. A
SCALE | **SHEET 1 OF 2**

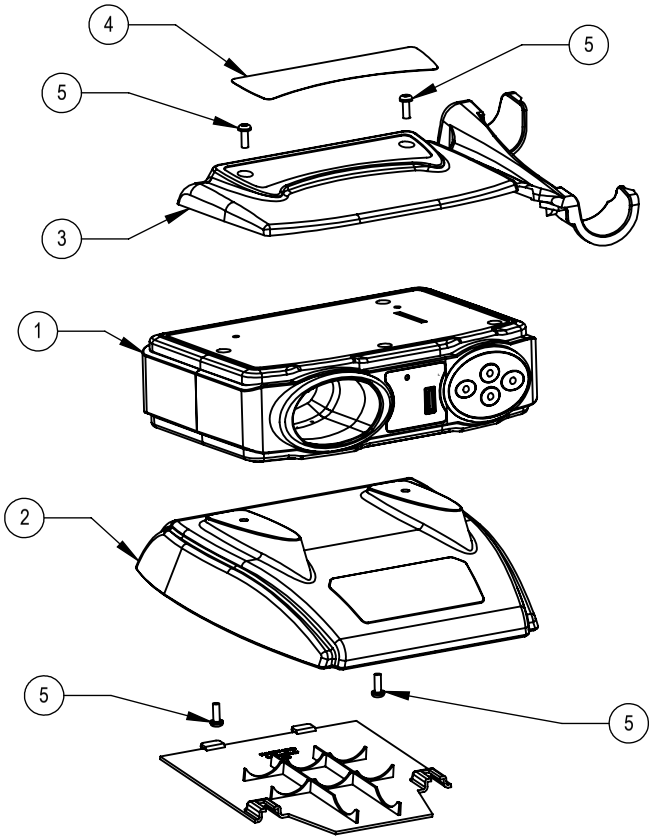
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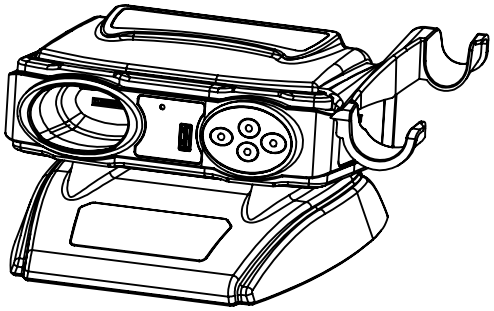
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Materials List

Item #	BioVision P/N	ITEM DESCRIPTION	QTY	UOM
1	BVT01097-01001	NeedleCam HD	1	ASSY
2	BVT01097-05101	Horrizontal Stand	1	ASSY
3	BVT01097-06001	Handpiece Cradle	1	ASSY
4	BVT51097-06001	Handpiece Cradle Label	1	ea
5	BVT86000-64030	Screw #6-32x3/8 Phil Pan Head Zinc	4	ea

ECO #	Description	Date	REV.

ENGINEERING CHANGE RECORD

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Dimension are in inches.
TOLERANCES ARE:
DECIMALS .XX: +/- .010 .XXX: +/- .005
ANGLES .XX: +/- 0.5 deg

MATERIAL N/A

FINISH N/A

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APPROVALS		DATE
MODELED	Pitzer	12-18-2014
DRAWN	Pitzer	12-18-2014
CHECKED	Korte	12-18-2014
RESP ENG	Sanso	12-18-2014
QUAL ENG	Ray	12-18-2014

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NeedleCam HD
Image Capture Box

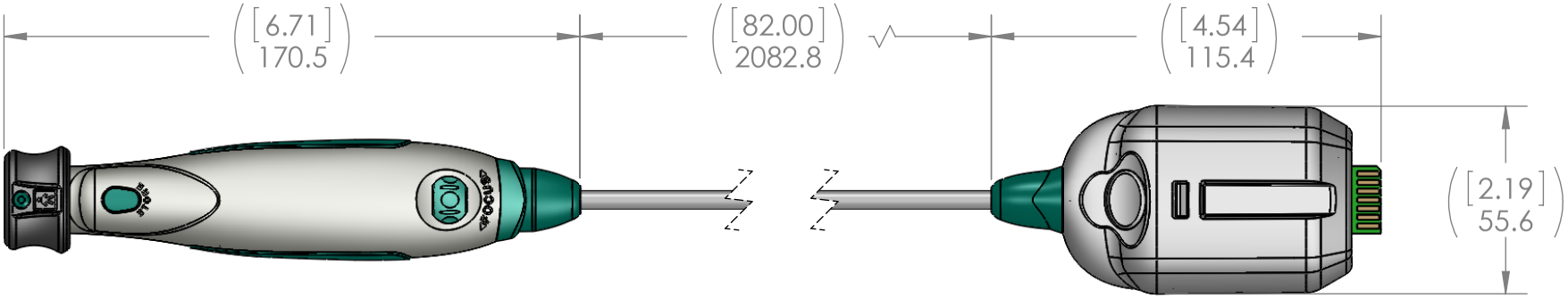
SIZE A | DWG. NO. BVT01097-00001 | REV. A

SCALE | SHEET 2 OF 2

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ANGLES: +/- 0.5 deg

MATERIAL: N/A

FINISH: N/A

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APPROVALS		DATE
MODELED	Pitzer	12-18-2014
DRAWN	Pitzer	12-18-2014
CHECKED	Korte	12-18-2014
RESP ENG	Sanso	12-18-2014
QUAL ENG	Ray	12-18-2014

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Connector Handpiece Assy

SIZE: A | DWG. NO. BVT01097-03001 | REV. A

SCALE | SHEET 1 OF 2

BVT92100-04001 A.slddrt

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(b)(4) Confidential and Proprietary Information

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Labeling (Manual): The intended use of the modified device has not changed as a result of the modification(s). The manual includes the same indications for use, contraindications and safety information as the predicate device. The manual has been updated to show the specific mechanics of the modified device.

- BVT93597-01001 Manual

Product Labeling: The product labeling has been updated for the new device configuration but as maintained the safety labeling that was included in the unmodified device. The following is a list of the labels included in the submission.

- BVT50197-01001 – Back Label
- BVT51097-01002 – Top Label
- BVT51097-01004 – Front Label – Right Side
- BVT51097-01005 – Front LED Label
- BVT51097-03001 – Handpiece Connector BioVision Label
- BVT51097-05101 – Logo Label – Horizontal Stand
- BVT51097-06001 – Handpiece Cradle Label
- BVT51897-01001 – NeedleCam HD Serial Label
- BVT51897-03002 – Handpiece Serial Label
- BVT89597-00001 – NeedleCam HD Shipping Label
- BMT89597-00001 – OnPoint Shipping Label

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BIO VISION Technologies, LLC



NeedleCam HD

MediaCaptureUSB

BioVision Technologies, L.L.C.

Model: 1080L

Operation and Service Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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BioVision Technologies
NeedleCam HD™ 1080L
Integrated Visualization System
with MediaCapture USB

Operation and Service Manual

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Golden, Colorado 80401
USA

Tel. 303-237-9608
Fax. 303-237-0757

biovisiontech.com

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IMPORTANT

The Biovision Technologies *NeedleCam HD*™ Integrated Visualization System is indicated to provide illumination and visualization of anatomy in an interior cavity of the body through a natural or surgical opening. This device is indicated for diagnostic and operative arthroscopic and endoscopic procedures. The device is to be used by a trained physician for the indicated uses only.

This manual describes the recommended procedures for preparing and operating the *NeedleCam HD*™. It does not describe how any medical procedure is to be performed on a patient with this instrument.

Read all instructions in this manual carefully before using the *NeedleCam HD*™ Integrated Visualization System.

Carefully follow all safety instructions to prevent injury to the user or patient, fire hazards, electrical shock, and damage to the device.

To maintain this device in optimal conditions, follow all recommendations in this manual for handling, cleaning, and storage.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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1. Introduction

Thank you for your purchase of the *NeedleCam HD*™ Imaging System from BioVision Technologies. The *NeedleCam HD*™ is designed and built to give you the latest technology and the best performance for your practice. This manual will help you make the most of your equipment investment.

1.1 The NeedleCam HD™ Integrated Visualization System

The *NeedleCam HD*™ system combines several essential surgical requirements into a single compact & portable package:

LED Light Source

By employing state-of-the-art light emitting diode technology, BioVision Technologies' proprietary LED Light Source incorporates high efficiency and low heat image illumination.

Proprietary High Definition Camera System

The *NeedleCam HD*™ system uses high-resolution 1080i digital display technology. A quick-release optical connector that adapts to a wide variety of BioVision Technologies' surgical endoscopes. BioVision Technologies' proprietary single cable design eliminates the complexity and cost of the traditional dual cable system approach.

Multiple Video Outputs

Multiple Output options on the *NeedleCam HD*™ system allow connection to larger High Definition video monitors by HDMI or RGB Component connections.

MediaCaptureUSB

A full-featured, fully-integrated image capture system is included in every *NeedleCam HD*™ system. Every *NeedleCam HD*™ has the capability to capture still images, and full-resolution video. Using the popular USB Flash Drive format, MediaCaptureUSB enables users to quickly and conveniently document their procedures. Using the Preview feature of the NeedleCam HD™ operating system you can browse captured media, delete images or transfer images to an external storage device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Disposable Fiberoptic Endoscopes

The *NeedleCam HD*™ Imaging system uses BioVision Technologies' proprietary scope coupling system. Only scopes provided by BioVision will work with this imaging system. A wide variety of one time use endoscopes are available from BioVision Technologies for many different procedures. Each endoscope is designed specifically for its intended use. Generic visualization endoscopes are available in a variety of diameters, lengths, and viewing angles.

USB Ports

The *NeedleCam HD*™ Imaging system has three USB ports that can be used for USB Flash Drives, Keyboards, or Mice. Note: The system will only recognize one USB Flash Drive at a time.

1.2 Indications for Use

The *NeedleCam HD*™ Integrated Visualization 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.

1.3 Contraindications

The *NeedleCam HD*™ Integrated Visualization System is contraindicated for use in applications where high intensity light might damage tissue such as neonate transillumination and some opthalmic procedures. For other contraindications, consult the literature accompanying the instrumentation utilized with this device.

1.4 Regulatory Compliance

Federal law restricts this device to sale by or on order of a physician licensed by the law of the state or country in which they practice; to use or order the use of this device.

- The *NeedleCam HD*™ Integrated Visualization System complies with all regulations to be marketed in the United States of America, Korea, and the European Union.
- This device complies with IEC 60601-1 and all collateral standards.
- This device complies with part 15 of the FCC rules.
- This device complies with the Medical Device Directive (Council Directive 93/42/EEC).
- Electromagnetic Compatibility (IEC 60601-1-2)
- This device complies with the Waste Electrical and Electronic Equipment Directives

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Guidance and Manufacturer's Declaration- Electromagnetic Emissions		
The NeedleCam HD™ is intended for use in the electromagnetic environment specified below. The customer or the user of the NeedleCam HD™ should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The NeedleCam HD™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The NeedleCam HD™ is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration- Electromagnetic Immunity			
The NeedleCam HD™ is intended for use in the electromagnetic environment specified below. The customer or the user of the NeedleCam HD™ should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+ 4 kV contact + 8 kV air	+ 40 kV contact + 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	+ 2 kV for power supply lines +1 kV for input/output lines	+ 2 kV for power supply lines +1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% UT(>95% dip in UT for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 sec.	100% dip for 0.5 cycles 60% dip for 5 cycles 30% dip for 25 cycles 100% dip for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NeedleCam HD™ requires continued operation during power mains interruptions, it is recommended that the NeedleCam HD™ be powered from an uninterruptible power supply or battery.
Power Frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the ac mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration- Electromagnetic Immunity			
The NeedleCam HD™ is intended for use in the electromagnetic environment specified below. The customer or the user of the NeedleCam HD™ should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V rms 150 kHz to 80 MHz outside of ISM bands 10Vrms 150 kHz to 80 MHz in ISM bands 10 V/m 80 MHZ to 2.5 GHz	10 V rms 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the NeedleCam HD™ including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = (3.5/3)\sqrt{P}$ $d = (3.5/3)\sqrt{P}$ 80 MHz to 800 MHZ $d = (7/3)\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 1080L is used exceeds the applicable RF compliance level above, the NeedleCam HD™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the NeedleCam HD™.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

Recommended separation distances between portable and mobile RF communications equipment and the NeedleCam HD™			
The NeedleCam HD™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NeedleCam HD™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NeedleCam HD™ as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter**		
	150kHz to 80MHz	**80MHz to 800MHz**	**800MHz to 2.5GHz**
0.01	0.035	0.035	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.7
10	1.12	1.12	2.21
100	3.5	3.5	7
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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1.5 Warranty Information

The BioVision Technologies capital equipment products, *NeedleCam HD™* Integrated Visualization System, and the camera head when delivered to the end user in new condition in the original container, is warranted to be free from defects in material or workmanship for one year from the date of shipment from Biovision Technologies, LLC. facility in Golden, Colorado to the end user.

The BioVision Technologies Accessory products, Surgical Endoscopes, Hand tools, and Fiber Optic Cables, when delivered to the end user in new condition in the original container, is warranted to be free from defects in material or workmanship for 90-days from the date of shipment from BioVision Technologies, LLC. facility in Golden, Colorado to the end user.

Within the above listed time periods, parts that are returned, freight prepaid, to BioVision Technologies LLC ("BioVision Technologies or BioVision") and are determined by BioVision Technologies to be defective will be repaired or replaced by BioVision Technologies without charge for parts, labor, or return ground shipping costs. BioVision Technologies will make every effort to accomplish this repair or replacement within a reasonable time. After the warranty period, you must pay all charges for repair and replacement. This warranty does not cover products intended for single patient use beyond the initial use or consumable items.

The above actions by BioVision Technologies shall constitute your exclusive remedy and BioVision Technologies' sole obligation under this warranty. BioVision Technologies shall not be responsible for warranty claims made after the warranty period. To obtain warranty repair service, you must contact Biovision Technologies to obtain a Return Material Authorization ("RMA") number, then return the product, freight prepaid, to BioVision Technologies or to a service facility authorized by BioVision Technologies. The RMA number and a complete explanation of the problem must be included with the product being returned to BioVision Technologies for warranty service. The product to be repaired must be returned in its original box and packaging, or a similar box and packaging affording an equivalent degree of protection. Upon completion of repairs, BioVision Technologies will return the product to the end user, freight prepaid.

The warranty period for replacement parts shall begin upon shipment of same, but shall in no event exceed the warranty period of the defective part. BioVision Technologies shall have no liability or obligation for a product that has been subjected to any of the following: failure caused by or attributable to Acts of God, improper use, abuse, negligent care or handling, accident, faulty installation, improper cleaning, improper maintenance, or other indications of excess voltage. This warranty is also void if the product has been repaired or modified without prior written authorization from Biovision Technologies, if the end-user has failed to follow the instructions or heed the warnings or specifications in the Operation and Care Manual, or if the product's serial number has been altered or removed.

EXCEPT FOR THE FOREGOING WARRANTIES, BIOVISION TECHNOLOGIES HEREBY DISCLAIMS AND EXCLUDES ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY AND/OR ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. BIOVISION TECHNOLOGIES HEREBY DISCLAIMS ANY REPRESENTATIONS OR WARRANTY THAT THIS PRODUCT OR ANY OF ITS PARTS IS COMPATIBLE WITH NON-BIOVISION TECHNOLOGIES PRODUCTS OTHER THAN VIDEO EQUIPMENT ATTACHED TO ITS VIDEO OUTPUTS, AS DESCRIBED IN THE OPERATOR'S MANUAL. THE LIABILITY OF BIOVISION TECHNOLOGIES, IF ANY, AND PURCHASER'S SOLE AND EXCLUSIVE REMEDY FOR DAMAGES FOR ANY CLAIM OF ANY KIND WHATSOEVER, REGARDLESS OF THE LEGAL THEORY, SHALL NOT BE GREATER IN AMOUNT THAN THE PURCHASE PRICE OF THE PRODUCT SOLD BY BIOVISION TECHNOLOGIES THAT CAUSED ANY ALLEGED DAMAGE. IN NO EVENT SHALL BIOVISION TECHNOLOGIES BE LIABLE TO PURCHASER FOR ANY SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OF ANY KIND.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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1.6 How to Use This Manual

The intention of this document is to convey the proper and prescribed operation and care of the *NeedleCam HD*™ 1080L Integrated Visualization System.

This manual adheres to a set of conventions to help you easily find the information you need and inform you of important information that will help you efficiently and effectively use your equipment.

Sections and sub-sections are noted as follows:

1. Section Title

1.1 Sub-section title

Special and important information is called out using notes and warnings. Notes usually pertain to a recommended protocol that will help extend the life of your equipment. Warnings pertain to protocols that delineate appropriate actions which maintain a safe and healthy work environment. Notes and warnings are called out in the following manners:

Note: This is a note.

WARNING: This is a warning.

1.7 List of Symbols (used in this manual and product labels)


Hazard Warning.


Attention: Read Operating Manual for Warnings, Precautions, and Instructions for Use.


Caution - High Voltage


Caution - Hot


Type BF Applied Part

IPXØ Not Protected Against the Ingress of Water



Storage Humidity



Transport Temperature

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Alternating Current


Federal Communications Commission Mark


Date of Manufacture


WEEE Compliant


European CE Mark



UL Testing Laboratories

AAMI ES60601-1 MEDICAL ELECTRICAL EQUIPMENT, PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE
CSA C22.2 NO. 60601-1:08 MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE
IEC 60601-1 3RD ED. MEDICAL ELECTRICAL EQUIPMENT PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE
IEC 60601-2-18 MEDICAL ELECTRICAL EQUIPMENT. PT. 2-18, PARTICULAR REQUIREMENTS FOR SAFETY OF ENDOSCOPIC EQUIPMENT

2. Product Specifications

The following section describes the components and features of the *NeedleCam HD*™ system.

2.1 Contents

The following components are included in your *NeedleCam HD*™ system. These components form the *NeedleCam HD*™ system and should be treated as ME Equipment per IEC 60601-1. Check to see that you have all of these components before proceeding:

NeedleCam HD™ Image Capture Box
NeedleCam HD™ Endoscopic Camera Handpiece
External Power Supply
Operation and Service Manual

Applied parts of equipment used in conjunction with this system must be Type BF or Type CF applied parts.

If any of these components are missing, contact BioVision Technologies immediately using the contact information below.

BioVision Technologies
221 Corporate Circle Suite H
Golden, Colorado 80401
USA

Phone: 303.237.9608
Fax: 303.237.0757
Email: info@biovisiontech.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Image Capture Box

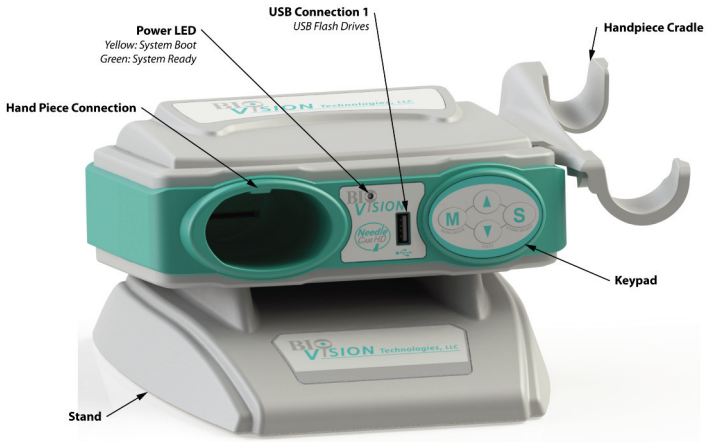


Figure 2.2.1-A: Image Capture Box

Rear View

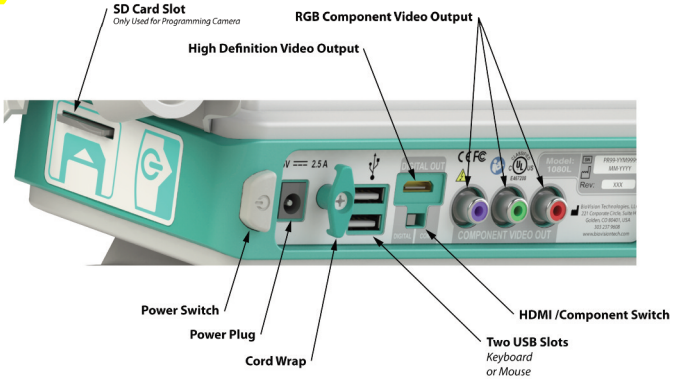


Figure 2.2.1-B: Rear View

Keypad Details

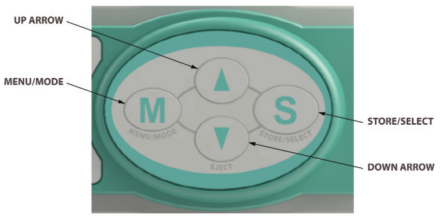


Figure 2.2.1-C: Keypad Details

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Camera Handpiece



Figure 2.2.1-D: Handpiece Front Details

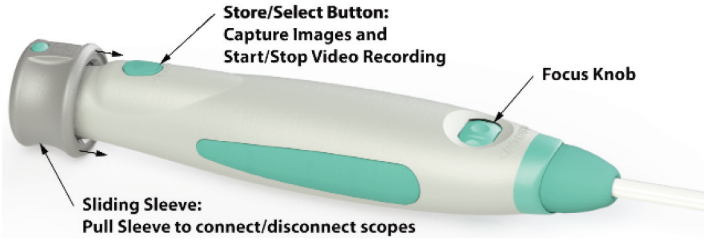


Figure 2.2.1-E: Handpiece Basic Functions

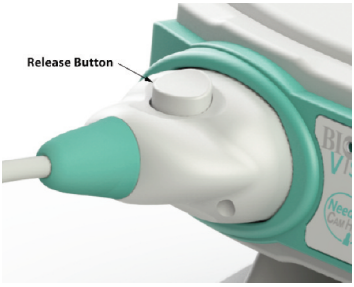


Figure 2.2.1-F: Connector Details

NeedleView™ Scope and Camera Handpiece

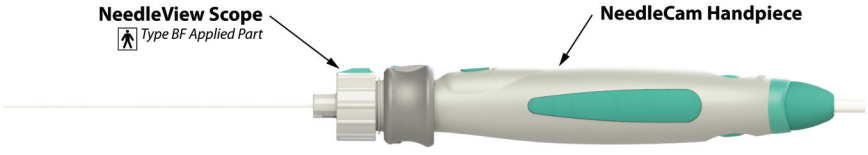


Figure 2.2.1-G: Handpiece With Scope

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2.2.2 NeedleCam HD™ Technical Specifications

Electrical

Input voltage:	5VDC
Input current:	2.5A maximum.
Power connector:	2.0 mm DC Power Jack
Classification:	IEC60601-1 Class I
Mode of operation:	Continuous

Power Supply

Input voltage:	100-240VAC, 50-60Hz (US input voltage)125VAC
Input current:	3.0-1.5A maximum.
Output voltage:	5V DC
Output current:	4.0A DC
Power connector:	2.0 mm DC Power Jack
Classification:	IEC60601-1 Class I
Mode of operation:	Continuous

Environmental

Operating altitude:	-304 to 3657m(-1000 to 12000 ft) MSL.
Operating temperature:	0ºC to 30ºC (-32ºF to 86ºF).
Operating humidity:	0% to 95% RH, non-condensing.
Storage/transport altitude:	-304 to 10668m (-1000 to 35000 ft) MSL.
Storage/transport temperature:	0ºC to 50ºC (-32ºF to 122ºF).
Storage/transport humidity:	0% to 95% RH, non-condensing.

Video

Output video format:	
Video output 1:	RGB 1080i/60 Component
Video output 2:	Digital 1080i HDMI Compatible

Light Source

Type:	LED
Power:	1W

MediaCaptureUSB

Storage media:	USB Flash Drive
Still image file format:	JPEG
Still image size:	1920 x 1080 pixels.
Video file format:	H.264
Video size/frame rate:	640x480 pixels/30fps.

Compatible Camera Attachments

*Needle*Cam HD™ Camera Hand Piece

Product Life *7 years*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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2.3 Safety Information

General requirements for the safe use of the device:

- It is important that you read, understand, and comply with all of the following safety precautions, markings, labeling, and all accompanying literature.
- Failure to follow these precautions could result in injury to the patient or user, or damage to the *NeedleCam HD*™ system.
- Before each use, check the outer surface of the endoscope and endoscopically-used accessories to ensure there are no unintended rough surfaces, sharp edges, or protrusions that may cause a safety hazard to the patient or user; or cause damage to the equipment and other accessories.
- In the event of use with other surgical tools such as shavers, care shall be taken to avoid damage to the endoscope or any endoscopically used accessories. All damaged instruments shall be discarded immediately.
- In the event of a loss of system function during a procedure, no further visualization is necessary and the procedure is ended. The physician shall remove the endoscope and proceed with closure or further patient care as needed. Further endoscopic examination shall only be performed with a fully functional system, for which a backup unit is recommended.
- Before each use and after changing viewing modes, ensure that the view observed through the endoscope is the live—not stored—image and that the image has the correct orientation.

To avoid personal injury and damage to this device:

- Always place and keep the *NeedleCam HD*™ unit on a flat, level, and secure surface.
- In the event of suspected damage or failure, DO NOT OPERATE. Have the device inspected by qualified personnel.
- When the NeedleCam HD™ system has reached the end of its useful life, turn the unit in to a local electronics waste recycle center or EEE center, as required by Directive 2012/19/EU. Do NOT dispose of unit in general waste collection.

To avoid fire hazard and electrical shock:

- DO NOT operate the device outside of the specified input voltage range.
- Only use medical-grade power cords with the NeedleCam HD™ system.
- Connect to a properly grounded hospital-grade outlet only.
- DO NOT operate the *NeedleCam HD*™ system in an explosive atmosphere (e.g. in the presence of flammable anesthetics, etc.).
- The *NeedleCam HD*™ system does not have any field-replaceable parts. DO NOT disassemble or open covers or panels. Opening the unit will void the manufacturer's warranty and introduce a risk of shock, injury, or death.
- DO NOT operate this product if there are signs of tampering or any of the covers are removed.
- DO NOT allow foreign objects inside of the device.
- Before performing any kind of maintenance (e.g. cleaning the *NeedleCam HD*™ system, moving, etc.), always perform the following:
  - Unplug the power cord.

IPXØ

- Do not allow spilling of liquids on the *NeedleCam HD*™ system.
- Do not immerse any of the components in liquids.
- Do not operate in wet or damp conditions.
- If any maintenance or repair is needed beyond superficial cleaning, contact BioVision Technologies or your authorized service representative.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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To isolate the NeedleCam HD from mains power, unplug the power supply from the wall socket. Always unplug the power cord if:

- The device has been exposed to moisture, liquids have been spilled on the device, the device or any of its components have been soaked or immersed in liquids.
- The device has been dropped.
- The device does not operate properly, the device does not turn on, or the performance of the device is noticeably different.
- The device displays signs of tampering or damage, such as damage to the power supply, broken enclosures, etc.

WARNING: In the event of use with other energized endoscopically-used instruments and accessories, the PATIENT LEAKAGE currents may be additive.

WARNING: Possible explosion if used in the presence of FLAMMABLE ANESTHETICS or other EXPLOSIVE GAS MIXTURES.

WARNING: This device is not intended to be used in the presence of HIGH FREQUENCY SURGICAL EQUIPMENT.

WARNING: Awareness of the possibility of a gas embolism whenever compressed gases are used in a patient procedure. To minimize the risk, you must verify that adequate space exists for the egress of any patient applied gases.

WARNING: DO NOT look directly into the light emitting windows of the endoscope or hand piece. This may result in eye damage.



WARNING: Do not touch the light port of the hand piece upon disconnection. The tip of the port may become hot after long periods of use.

WARNING: DO NOT IMMERSE the camera handpiece in liquids of any kind, personal injury or damage to the device may result.

WARNING: There is a possibility of reciprocal interference for devices sensitive to high levels of light exposure.

WARNING: All USB Ports are designed to accept Keyboards, Mice, and USB Flash Drives. Any other devices may introduce the risk of shock, injury, or death.

WARNING: No modifications of this equipment are allowed.

WARNING: DO NOT point a laser directly into the camera or endoscope.

WARNING: The power cord is a tripping hazard. DO NOT route the cord in a way that someone could trip over the cord.

WARNING: Products used in conjunction with this system must be type BF or CF.

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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To avoid electromagnetic interference:

- Special precautions are required regarding the electromagnetic compatibility (EMC) of the *NeedleCam HD™* system. The system needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile radio frequency (RF) communications equipment can affect any medical electrical equipment including the *NeedleCam HD™* system.
- This device should not be used adjacent to or stacked with other equipment. Should use adjacent to other equipment become necessary the system should be observed to verify normal operation in that configuration.

"Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department."

3. Setup and Basic Usage

The following section describes how to set up and use the *NeedleCam HD™* system for surgical procedures.

3.1 Setup

Proper initial setup is essential to providing you and your staff the best access to operational and visual performance while conducting procedures.

3.1.1 NeedleCam HD™ System

For best performance, always operate and keep the *NeedleCam HD™* system on a flat, level, and secure surface. Images on the Video Monitor are best viewed at an angle perpendicular to the display.

Do not tilt the *NeedleCam HD™* system.

3.1.2 Attaching External Video Devices

The *NeedleCam HD™* system has connections for multiple video outputs. Any monitor used with this system must have either HDMI or Component RGB connections.

The *NeedleCam HD™* system can be connected to a standard video monitor with either a Mini HDMI connector or RGB Component connectors. Consult your video monitor manual for the corresponding connections. In order to take full

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advantage of the benefits offered by our high definition system you will need a monitor capable of displaying a high definition signal.

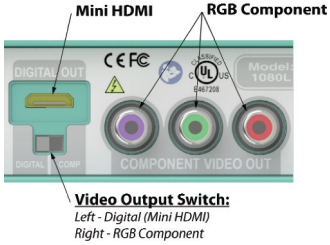


Figure 3.1.2-A: Video Out Details

To make these connections, plug the connecting cable(s) into the video output(s) on the rear of the *NeedleCam HD™* and the corresponding video input(s) of the external devices.

Note: In order to output a specific signal, turn the power off and the "signal selection switch" at the back of the device should be slid toward the signal label that you are wanting to output *(e.g. for Digital output, the switch should be to the left "DIGITAL" side)(HDMI).* The power can then be turned on.

Note: The system will only export one video signal at a time. If the switch is to the left "DIGITAL" side, only the high definition signal will be exported. If the switch is to the right "COMPONENT" side, only the component signal will be exported.

3.1.3 Attaching a Camera Handpiece and Endoscope

The camera handpiece attaches via a PCB electric connector. This connector seats in the receptacle on the front of the unit (See also: § 2.2.1-F Connector Details).

Before connecting a camera handpiece to the *NeedleCam HD™* system, the camera hand piece must be appropriately cleaned.

Note: For best image quality and to ensure patient safety, verify that both ends of the camera hand piece are free of foreign particles.

Connecting the hand piece to the *NeedleCam HD™* system: The connector assembly fits into the port in only one orientation. Insert the connector assembly into the port until the retention tab clicks into place and the Release Button pops up.

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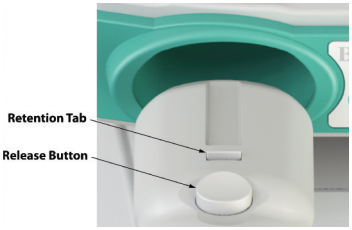


Figure 3.1.3-A: Connector Insertion Details

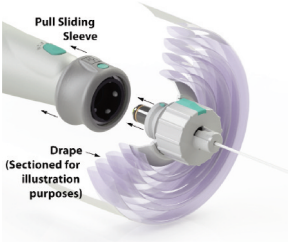


Figure 3.1.3-B: Scope Attachment Details

Connect the scope to the camera by pulling the sliding sleeve and inserting the scope. Ensure that the light port is aligned with the bottom of the camera. Release the sliding sleeve to secure the scope in place. The proper technique must be utilized in order to preserve the sterile field through the drape that is attached to each endoscope. See instructions in section 3.1.4 for the proper procedure for attaching a scope while maintaining the sterile field.

3.1.4 Attaching a Sterile Scope Within the Sterile Field

Attaching a sterile scope while preserving the sterile field requires two people. One person remains outside the sterile field and one person remains inside the sterile field. The non-sterile person holds the camera hand piece and pulls back the sliding sleeve. The sterile person takes the scope from the sterile packaging and inserts the back end into the camera hand piece while the sliding sleeve is pulled back. After proper alignment and connection has been achieved, the non-sterile person grabs the two white tabs on the end of the sterile drape and pulls both tabs down the hand piece and connection cable until the drape has been completely unfolded. After the drape has been unfolded, the sterile person can now handle the camera hand piece and remain

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inside the sterile field. Once the scope is attached and the drape is pulled into place, continue with the rest of the setup procedure.

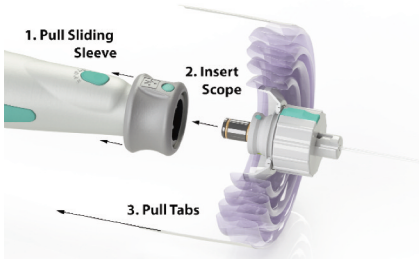


Figure 3.1.4-A: Sterile Scope Attachment Details

3.1.5 Focussing The Camera

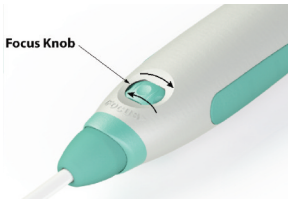


Figure 3.1.5-A: Focus Details

Turn the power on. The system will take about 30 seconds to power on and load the software. Hold the distal tip of the scope approximately 1.0 cm from a surface with fine details such as your palm or surgical drape. Turn the focus adjustment knob in either direction until the fine-detailed surface at the distal end of the scope comes into optimal focus on the video monitor. There are rotating limits at both the minimum and maximum focussing limits. If one of the limits has been hit and the image has not focused, rotate the focus knob in the opposite direction until the image comes into focus.

See also: § *3.2.1 Setup for Each Procedure*

3.2 Basic Usage

The *NeedleCam HD*™ Integrated Visualization System is indicated to be used in diagnostic and operative arthroscopic

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and endoscopic procedures. Examples of surgical use include but are not limited to procedures on the knee, shoulder, ankle, elbow, wrist, shoulder, temporomandibular joint (TMJ), spinal, opthalmic, ear/nose/throat (ENT), and the cervix.

3.2.1 Setup for Each Procedure

Ensure that the power supply being used is the one that is supplied with each system. Connect the supplied power supply to the *NeedleCam HD*™ system. Connect the other end of this supply to a power outlet that has also been approved for medical use. Position the equipment so that the power plug is easily accessible and can be easily un-plugged.

It is important to keep the system including the monitor out of the reach of the patient to avoid the patient experiencing harmful leakage currents.

Turn on the *NeedleCam HD*™ system by pressing the Power button (on the back of the unit to the right of the power cord plug in). Approximately thirty (30) seconds later, the software will activate in "Live Mode."

Note: These instructions are for basic usage of the *NeedleCam HD*™ system. Refer to section 1.2 for the "Indications for Use".
Note: More specific instructions on the functionality of "The Software," can be found in section 4

To store picture/video files, insert the USB flash drive into one of the USB ports. When the drive is successfully connected the USB symbol on the screen will change to indicate the system is ready to store image files.

Note: Files will only be stored to the first drive that is plugged in.
Note: Do Not plug in a USB Hub into any of the USB ports.

3.2.2 Power-Down Procedures

When you are finished using the *NeedleCam HD*™ system, turn off the system.

Always disconnect the *NeedleCam HD*™ system from its power source when performing any kind of maintenance (e.g. cleaning, etc.). Please refer to section 5 for proper cleaning and maintenance instructions

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3.2.3 Single-Use Endoscope Disposal

When disposing of the single-use endoscope and endoscope accessories, follow procedures for biologically hazardous materials.

4. The Software

The *NeedleCam HD*™ System contains an integrated software system that allows you to use any High Definition compatible external monitor as your display.

4.1 Software Basics

4.1.1 Monitor Interface

Since the software and display characteristics are built directly into the camera system, the information will display correctly with minimal setup required. The display is sectioned out into four (4) main areas. *(Heads Up Display, Patient Information, Camera View, and Image Gallery)*

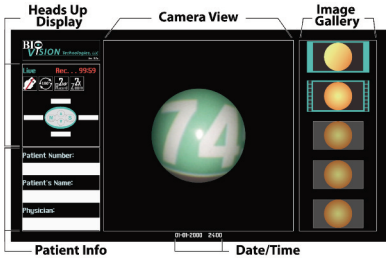


Figure 4.1.1-A: Monitor Interface Layout

4.1.2 Button Interface

There are four (4) buttons on the front of the *NeedleCam HD*™ system box that can control most functions of the system. The Heads Up display graphically shows the configuration and displays the function(s) of each button. Different modes within the software can change the function of each button. When there is a function assigned to a button, that function is shown in the Heads Up display.

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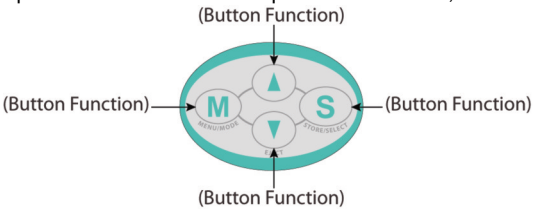


Figure 4.1.2-A: Monitor Interface Button Layout

4.1.3 Mode Menu

Most of the functions of this software can be accessed through the main menu. To access the menu simply press the button that is labeled "Menu/Mode" in the Button Interface section of the Heads Up display. Use the "▲/▼" keys to access each item. If there is no button labeled "Menu/Mode" another menu is currently being displayed and you will need to exit that menu.

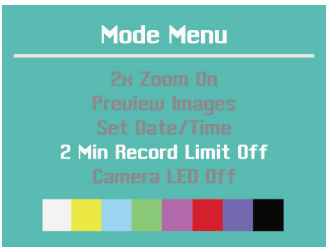


Figure 4.1.3-A: Monitor Interface Mode Menu

4.2 Entering Patient Information

Once the *NeedleCam HD*™ system has booted up and you have verified that a USB Flash Drive is correctly loaded into the front USB port, you can attach a keyboard to one of the USB ports on the back of the system. This will allow you to enter patient information into the three (3) fields located in the "Patient Info" section of the display. The information entered here will be tagged to each image and video file created. If the information is changed, the next file created will be tagged with the new set of information.

4.3 Modes

Our proprietary software does not require set up since it comes pre-loaded on every *NeedleCam HD*™ system and

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operates without the aid of an external computing source. There are several modes and options that are available through the menu system.

4.3.1 Live Mode
The *NeedleCam HD*™ system will start up in this mode. This is the mode where you are able to see what the camera is seeing. The image in the center of the screen is what the camera is currently seeing. You can take pictures/video from this mode. The *2X Zoom, 2 Min Record Limit,* and *Rotate 180°* modes are available as modifiers to the *Live Mode*.

4.3.2 Preview Mode
This mode is activated through the main menu. When active, this mode allows you to browse through the gallery of images and videos that have been captured on the user installed USB Flash Drive. The selected file shows up in the center of the screen; if the file is a video it can be played and paused. This mode can also be used to delete images from the USB Flash Drive.

4.3.3 2X Zoom Mode
When activated the size of the image in the center of the screen is doubled and the 2X Zoom Icon will appear in the Heads Up display. Depending on the size of the monitor, the expanded image may look grainy.

4.3.4 Set Date/Time - This mode allows you to set the system date and time and is available through the main menu. It is important to set this accurately because each image and video file created will have a date and time stamp associated with that file and will be ordered on the USB Flash Drive by date and time.

4.3.5 2 Min. Record Limit
When activated, this mode limits a single video recording to two (2) minutes and the 2 Min. Record Limit icon will appear in the Heads Up display. The record time indicator that appears when taking videos counts down from two (2)

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minutes.

4.3.6 Rotate 180°

The Rotate 180° function is only available through the main button panel on the front of the box. Check your on screen Heads Up display in "Live Mode" to find which button accesses this function. When this mode is activated, the image in the center of the screen is rotated 180 degrees and the Rotate 180° icon will appear in the Heads Up display.

4.3.7 Camera LED On/Off

The LED Light source on the Camera Hand Piece can be turned off for procedures where the light from the Hand Piece is not needed. This function is accessed through the Main Menu.

4.4 Color Bar

The Menu also contains a color bar that can be used to adjust your monitor's color balance. This will help you get the most accurate color rendering possible.

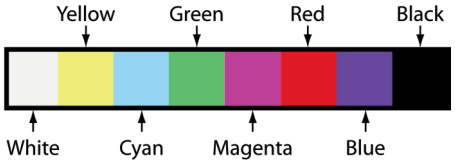


Figure 4.4-A: Monitor Interface Color Bar Details

5. Cleaning and Maintenance

The following section describes the proper method(s) for cleaning and maintaining your *NeedleCam HD*™ system.

Note: Never immerse or soak any part of the *NeedleCam HD*™ system or hand piece in any liquid, as this can cause significant damage not covered by the warranty.

5.1 General Cleaning of NeedleCam HD™ System

Use a lightly damp cloth. Wipe down the entire *NeedleCam HD*™ system with it.

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Allow the system to dry before using it again.

Any blood on the *NeedleCam HD*™ system can be removed using cotton or gauze soaked in alcohol.

5.2 Sterilization of the NeedleCam HD™

⚠ **CAUTION:** Do not sterilize the *NeedleCam HD*™ Integrated Visualization System or any of its components. Refer to cleaning section for instructions.

⚠ **WARNING:** RISK OF SHOCK. Do not autoclave. Do not soak or immerse in disinfecting fluids.

IPXØ Do not use or store disinfecting fluids above or on the *NeedleCam HD*™ Integrated Visualization System.

5.3 Storage Procedure

Store the NeedleCam system under appropriate storage conditions as stated in section 2.2.2. Wipe down the unit with a damp cloth and allow the system to dry prior to placing in storage.

6. Troubleshooting

Scenario

A: The unit will not operate. No lights on, with a blank screen.

1. Check all power connections to the *NeedleCam HD*™ system. Check the power cable connection to the wall outlet and the rear of the *NeedleCam HD*™ system.
See § 3.2.2 Setup for Each Procedure

2. Check the building breaker controlling the outlet you are using. You may need to consult the proper building administration to ensure power to your outlet.

3. Should these measures fail, please contact BioVision Technologies for technical support and/or service.

B: The image is blurry.

1. Rotate the focus ring to bring the image into focus.

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2. The scope, coupler or camera optics may be dirty. Please refer to the manual that came with the scope for proper care and cleaning.

3. The scope may be fogged. Wipe off front of scope with alcohol wipe.

C. There is no light or light output is low.

1. If light output seems low, check the connection between the light output on the camera and the scope for particles and foreign objects.

2. If there is no light, check the mode menu that the LED function is on.

3. If the output is still low or there is no light. Please contact your service representative.

6.2 LED Status Codes

Solid Yellow LED:	Loading Software
Solid Green:	System Ready
Flashing Green:	Software Failure

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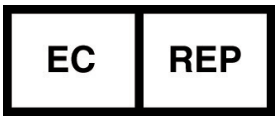
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Email: info@biovisiontech.com

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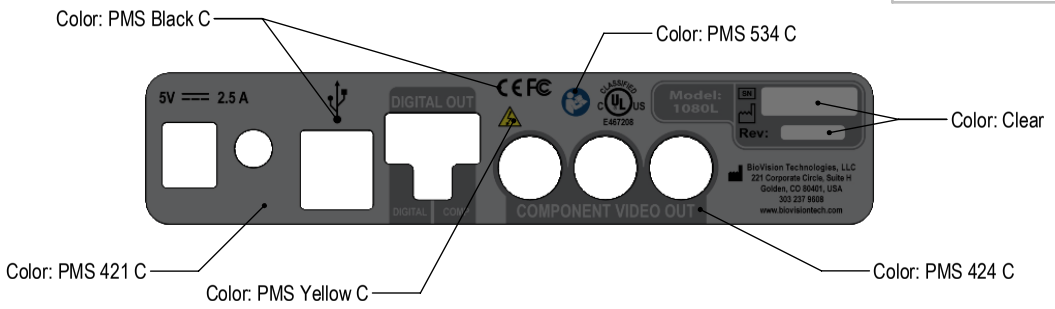
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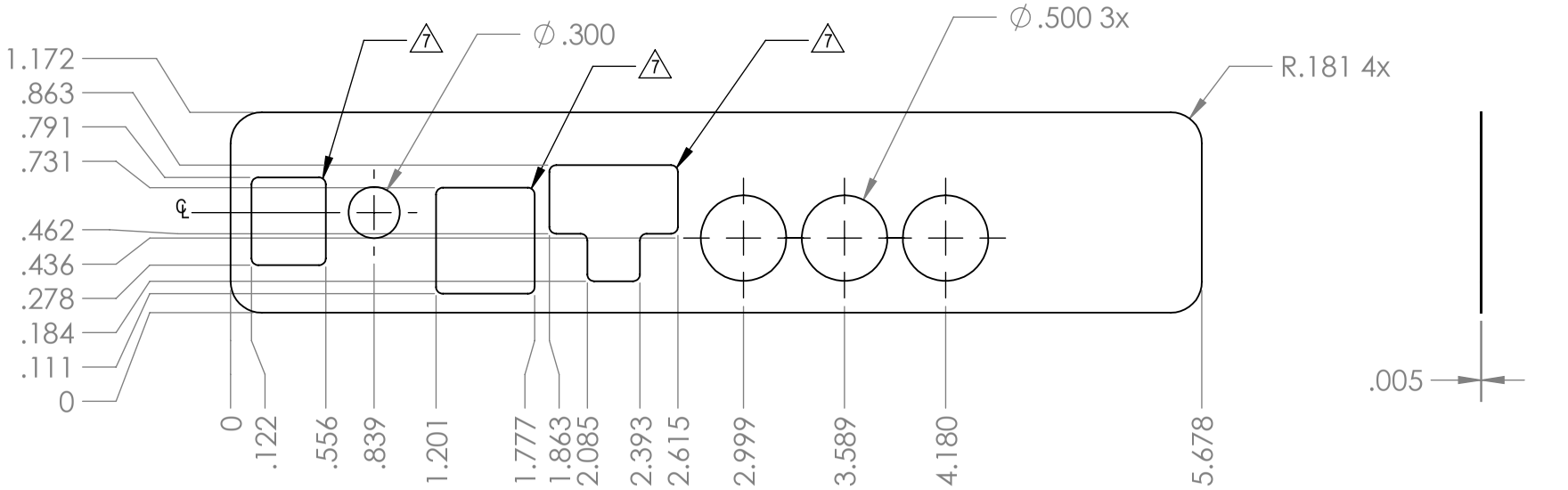
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2. Graphics to be controlled by CAD drawing: BVT51097-01001_Back Label.ai
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4. Additional colors: PMS 424C, PMS 534 C, Black, Yellow C
5. Material: .005" Sabic, Lexan 8B35 Matte Textured, or approved equivalant
6. Addhesive: .005" Optically Clear 3M 9483, or approved equivalant
7. Corner Radii: .040 in. unless otherwise noted.

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X3E	Changing Graphics - Iso Icons and SN area	10-31-2014	X3E
X3	INITIAL RELEASE	08-26-2013	X3

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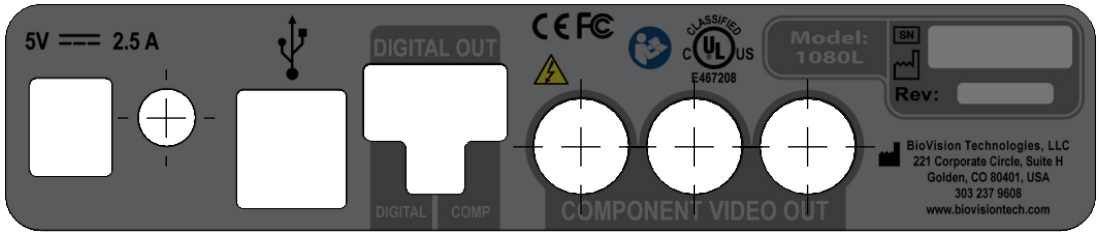
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RESP ENG	Sanso	10-31-2014
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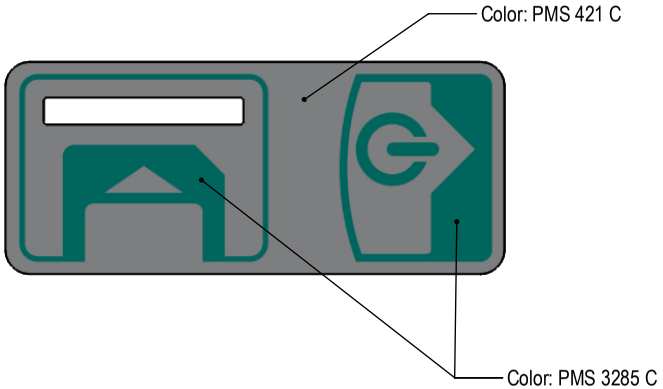
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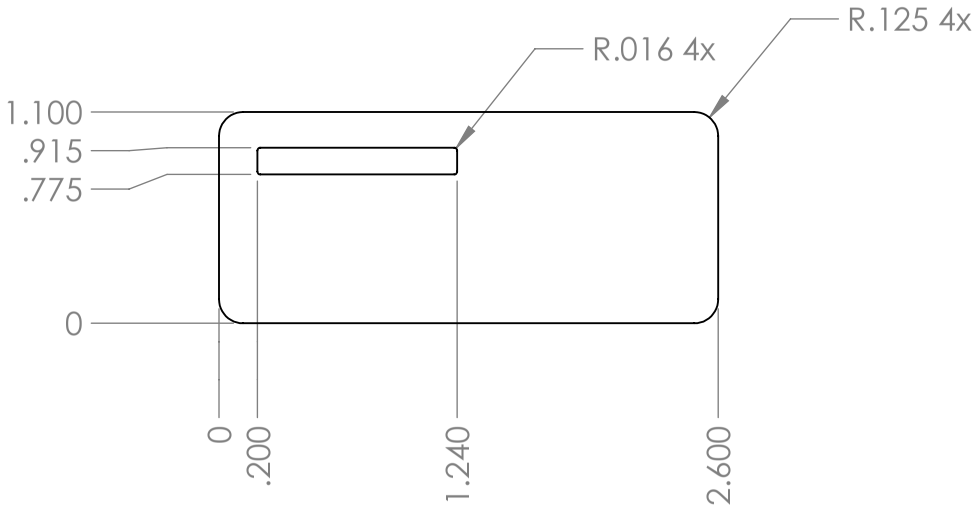
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4. Additional colors: PMS 3285
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6. Addhesive: .005" 3M 468 MP, or approved equivalant

ECO #	Description	Date	REV.
X3B	Modified Material Specifications	11-03-2014	X3B

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ANGLES .XX: +/- 0.5 deg

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FINISH: See Notes
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PART NO:
BVT51097-01002



SCALE 1.5 : 1

ECO #	Description	Date	REV.

ENGINEERING CHANGE RECORD

UNLESS OTHERWISE SPECIFIED
Dimension are in inches.
TOLERANCES ARE:
DECIMALS .XX: +/- .010 .XXX: +/- .005
ANGLES .XX: +/- 0.5 deg

MATERIAL: See Notes
FINISH: See Notes
DO NOT SCALE DRAWING

CAD GENERATED DRAWING,
DO NOT MANUALLY UPDATE

APPROVALS		DATE
MODELED	Pitzer	05-08-2013
DRAWN	Pitzer	11-03-2014
CHECKED	Korte	11-03-2014
RESP ENG	Sanso	11-03-2014
QUAL ENG	Ray	11-03-2014

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Top Label
NeedleCam HD - BioVision

SIZE A | DWG. NO. **BVT51097-01002** | REV. X3B
SCALE | **SHEET 2 OF 2**

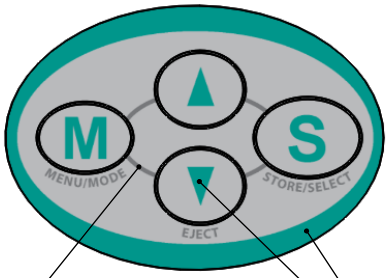
BVT92100-04001 A.slddrt

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-10065; Released by CDRH on 09-26-2016.

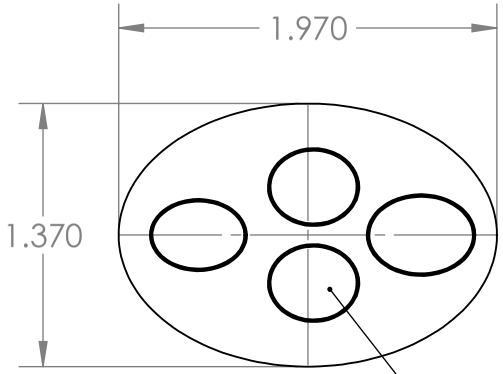
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PART NO:
BVT51097-01004



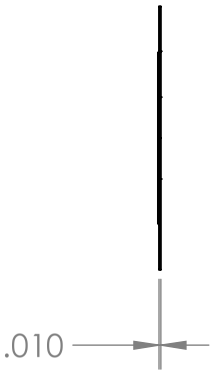
Color: PMS 424 C

Color: PMS 421 C



Die Line

Emboss Information On Page 2.



NOTES:

1. Geometry to be controlled by CAD model: BVT51097-01004_Front Label_Right Side.sldprt and control dimensions.
2. Graphics to be controlled by CAD drawing: BVT51097-01004_Front Label_Right Side.ai
3. Base color: White (Base), PMS 421 C
4. Additional colors: PMS 424, PMS 3285,
5. Material: .010" Sabic, Lexan 8B35 Matte Textured, or approved equivalant
6. Addhesive: .005" 3M 468 MP, or approved equivalant

ECO #	Description	Date	REV.
X3B	Modified Material Specifications	11-03-2014	X3B

ENGINEERING CHANGE RECORD

UNLESS OTHERWISE SPECIFIED Dimension are in inches.
TOLERANCES ARE:
DECIMALS .XX: +/- .015 .XXX: +/- .010
ANGLES .XX: +/- 0.5 deg

MATERIAL: See Notes
FINISH: See Notes
DO NOT SCALE DRAWING

CAD GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
MODELED Pitzer	05-08-2013
DRAWN Pitzer	11-03-2014
CHECKED Korte	11-03-2014
RESP ENG Sanso	11-03-2014
QUAL ENG Ray	11-03-2014

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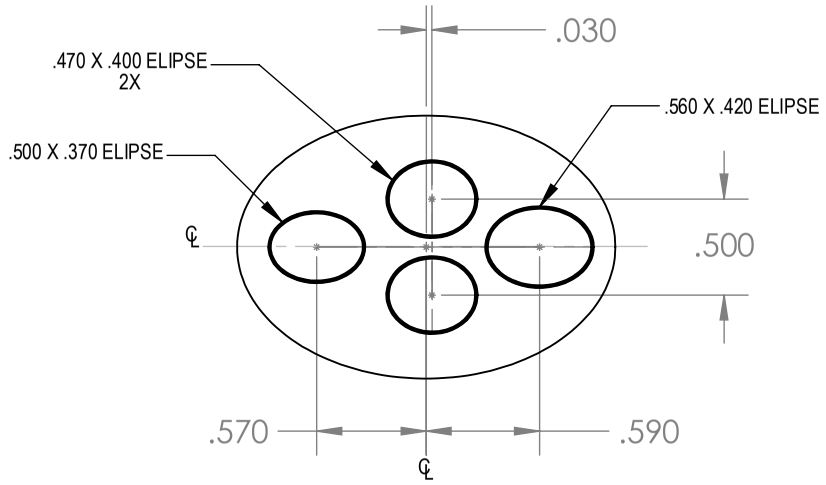
Front Label_Right Side
NeedleCam HD - BioVision

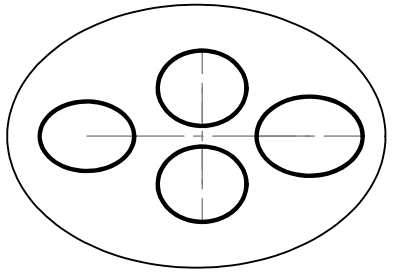
SIZE A | DWG. NO. BVT51097-01004 | REV. X3B
SCALE | SHEET 1 OF 3

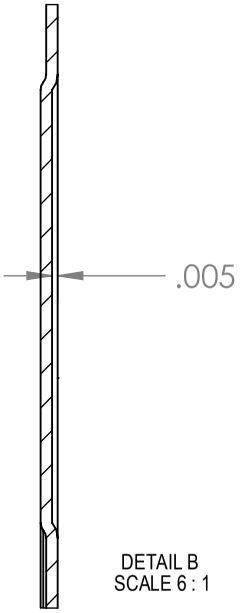
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
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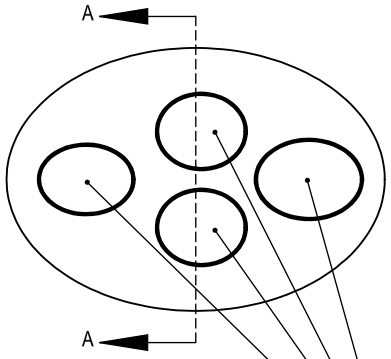
PART NO:
BVT51097-01004

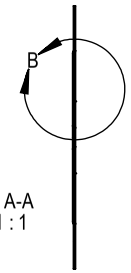






DETAIL B
SCALE 6 : 1





SECTION A-A
SCALE 1 : 1

Embossed Areas
No Adhesive in Embossed Areas.

EMBOSSING DETIALS

ECO #	Description	Date	REV.

ENGINEERING CHANGE RECORD

UNLESS OTHERWISE SPECIFIED
Dimension are in inches.
TOLERANCES ARE:
DECIMALS .XX: +/- .010 .XXX: +/- .005
ANGLES .XX: +/- 0.5 deg

MATERIAL: See Notes
FINISH: See Notes
DO NOT SCALE DRAWING

CAD GENERATED DRAWING,
DO NOT MANUALLY UPDATE

APPROVALS		DATE
MODELED	Pitzer	05-08-2013
DRAWN	Pitzer	11-03-2014
CHECKED	Korte	11-03-2014
RESP ENG	Sanso	11-03-2014
QUAL ENG	Ray	11-03-2014

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Golden, CO 80401
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Front Label_Right Side
NeedleCam HD - BioVision

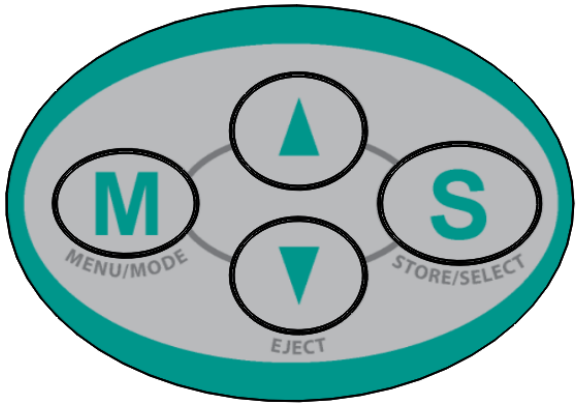
SIZE A | DWG. NO. BVT51097-01004 | REV. X3B
SCALE | SHEET 2 OF 3

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PART NO: **BVT51097-01004**



SCALE 1.5 : 1

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ECO #	Description	Date	REV.

ENGINEERING CHANGE RECORD

UNLESS OTHERWISE SPECIFIED
Dimension are in inches.
TOLERANCES ARE:
DECIMALS .XX: +/- .010 .XXX: +/- .005
ANGLES .XX: +/- 0.5 deg

MATERIAL: See Notes

FINISH: See Notes

DO NOT SCALE DRAWING

CAD GENERATED DRAWING,
DO NOT MANUALLY UPDATE

APPROVALS		DATE
MODELED	Pitzer	05-08-2013
DRAWN	Pitzer	11-03-2014
CHECKED	Korte	11-03-2014
RESP ENG	Sanso	11-03-2014
QUAL ENG	Ray	11-03-2014

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Front Label_Right Side
NeedleCam HD - BioVision

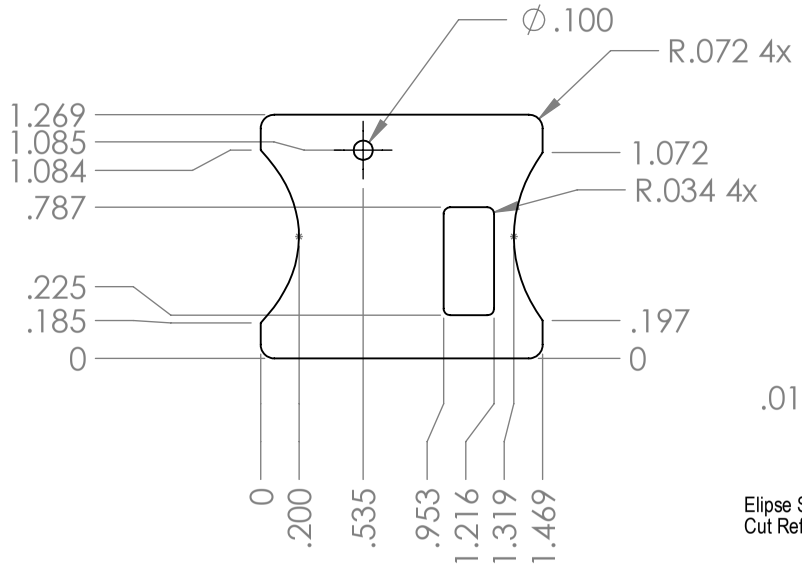
SIZE A | DWG. NO. BVT51097-01004 | REV. X3B

SCALE | SHEET 3 OF 3

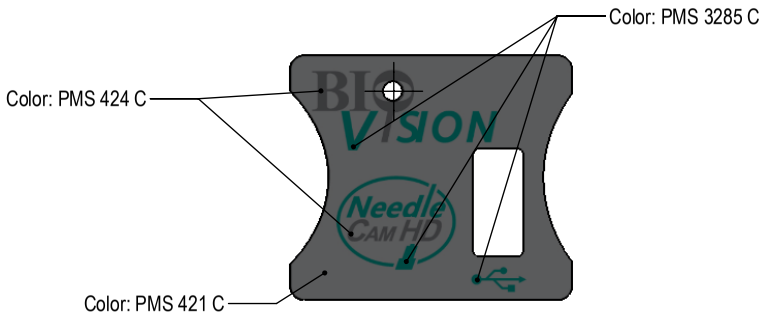
BVT92100-04001 A.slddrt

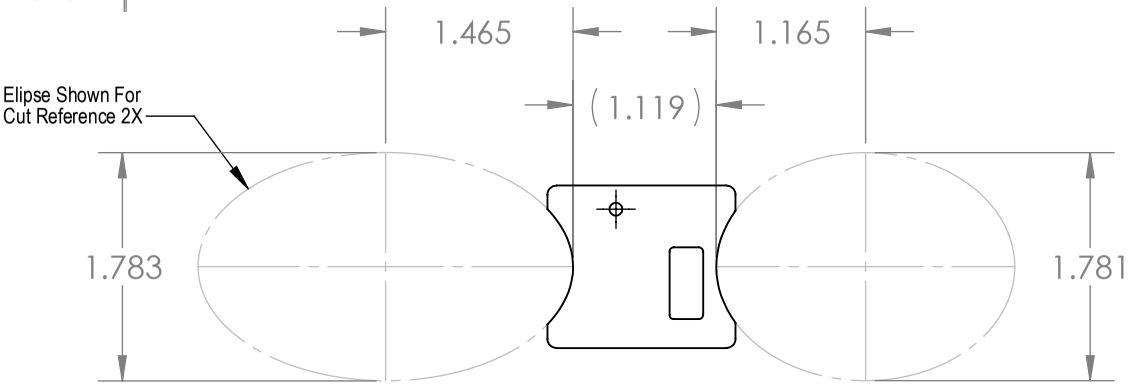
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PART NO:
BVT51097-01005









NOTES:

1. Geometry to be controlled by CAD model:
   BVT51097-01005_Front LED Label.sldprt and control dimensions.
2. Graphics to be controlled by CAD drawing:
   BVT51097-01005_Front LED Label.ai
3. Base color: White (Base), PMS 421 C
4. Additional colors: PMS 424, PMS 3285,
5. Material: .010" Sabic, Lexan 8B35 Matte Textured, or approved equivalant
6. Addhesive: .005" 3M 468 MP, or approved equivalant

ECO #	Description	Date	REV.
X3B	Modified Material Specifications	11-07-2014	X3B

ENGINEERING CHANGE RECORD

UNLESS OTHERWISE SPECIFIED
Dimension are in inches.
TOLERANCES ARE:
DECIMALS .XX: +/- .015 .XXX: +/- .010
ANGLES .XX: +/- 0.5 deg

MATERIAL: See Notes
FINISH: See Notes
DO NOT SCALE DRAWING

CAD GENERATED DRAWING,
DO NOT MANUALLY UPDATE

APPROVALS		DATE
MODELED	Pitzer	05-08-2013
DRAWN	Pitzer	11-07-2014
CHECKED	Korte	11-07-2014
RESP ENG	Sanso	11-07-2014
QUAL ENG	Ray	11-07-2014

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Front LED Label
NeedleCam HD - BioVision

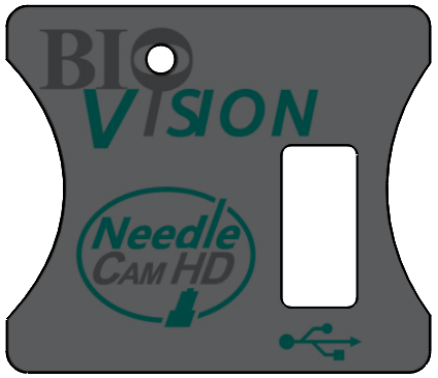
SIZE A | DWG. NO. BVT51097-01005 | REV. X3B
SCALE | SHEET 1 OF 2

BVT92100-04001 A.slddrt

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PART NO:
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ECO #	Description	Date	REV.

ENGINEERING CHANGE RECORD

UNLESS OTHERWISE SPECIFIED
Dimension are in inches.
TOLERANCES ARE:
DECIMALS: .XX: +/- .010, .XXX: +/- .005
ANGLES: .XX: +/- 0.5 deg

MATERIAL: See Notes

FINISH: See Notes

DO NOT SCALE DRAWING

CAD GENERATED DRAWING,
DO NOT MANUALLY UPDATE

APPROVALS		DATE
MODELED	Pitzer	05-08-2013
DRAWN	Pitzer	11-07-2014
CHECKED	Korte	11-07-2014
RESP ENG	Sanso	11-07-2014
QUAL ENG	Ray	11-07-2014

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221 Corporate Circle, Suite H
Golden, CO 80401
303-237-9608, Fax: 303-237-0757

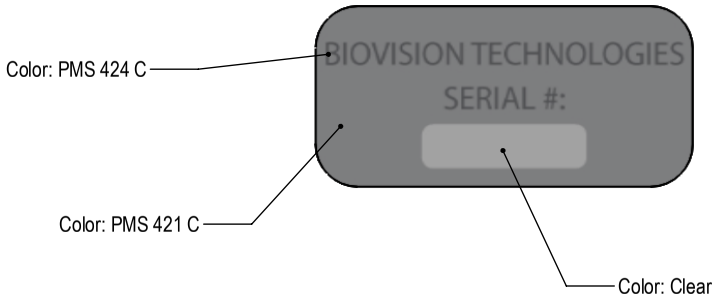
Front LED Label
NeedleCam HD - BioVision

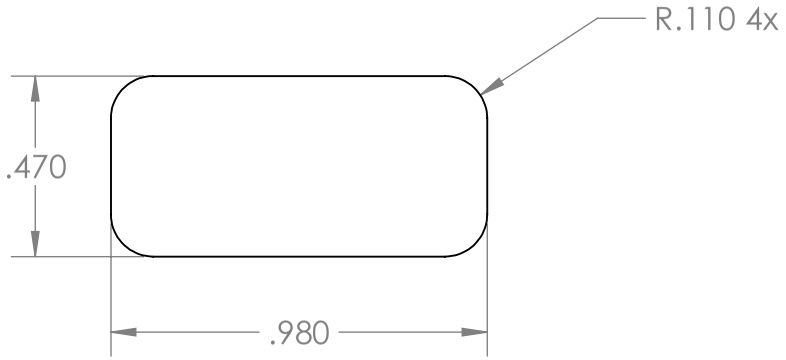
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DWG. NO.: **BVT51097-01005**
REV.: X3B
SCALE:
SHEET 2 OF 2

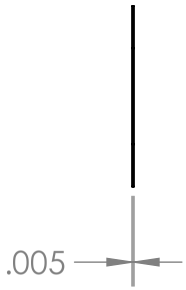
BVT92100-04001 A.slddrt

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PART NO:
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NOTES:

1. Geometry to be controlled by CAD model: BVT51097-03001_Connector BV Label.sldprt and control dimensions.
2. Graphics to be controlled by CAD drawing: BVT51097-03001_Connector BV Label.ai
3. Base color: White (Base), PMS 421 C
4. Additional colors: PMS 424C
5. Material: .005" Sabic, Lexan 8B35 Matte Textured, or approved equivalant
6. Addhesive: .005" Optically Clear 3M 9483, or approved equivalant

ECO #	Description	Date	REV.
X3B	Modified Material Specifications	11-07-2014	X3B

ENGINEERING CHANGE RECORD

UNLESS OTHERWISE SPECIFIED Dimension are in inches.
TOLERANCES ARE:
DECIMALS .XX: +/- .010 .XXX: +/- .005
ANGLES .XX: +/- 0.5 deg

MATERIAL: See Notes
FINISH: See Notes
DO NOT SCALE DRAWING

CAD GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS		DATE
MODELED	Pitzer	07-02-2014
DRAWN	Pitzer	11-07-2014
CHECKED	Korte	11-07-2014
RESP ENG	Sanso	11-07-2014
QUAL ENG	Ray	11-07-2014

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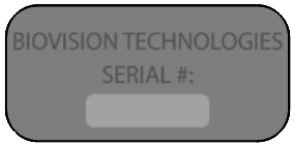
Connector BV Label
NeedleCam HD - BioVision

SIZE A | DWG. NO. BVT51097-03001 | REV. X3B
SCALE | SHEET 1 OF 2

BVT92100-04001 A.slddrt

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PART NO:
BVT51097-03001



SCALE 1.5 : 1

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ECO #	Description	Date	REV.

ENGINEERING CHANGE RECORD

UNLESS OTHERWISE SPECIFIED
Dimension are in inches.
TOLERANCES ARE:
DECIMALS .XX: +/- .010 .XXX: +/- .005
ANGLES .XX: +/- 0.5 deg

MATERIAL: See Notes

FINISH: See Notes

DO NOT SCALE DRAWING

CAD GENERATED DRAWING,
DO NOT MANUALLY UPDATE

APPROVALS		DATE
MODELED	Pitzer	07-02-2014
DRAWN	Pitzer	11-07-2014
CHECKED	Korte	11-07-2014
RESP ENG	Sanso	11-07-2014
QUAL ENG	Ray	11-07-2014

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221 Corporate Circle, Suite H
Golden, CO 80401
303-237-9608, Fax: 303-237-0757

Connector BV Label
NeedleCam HD - BioVision

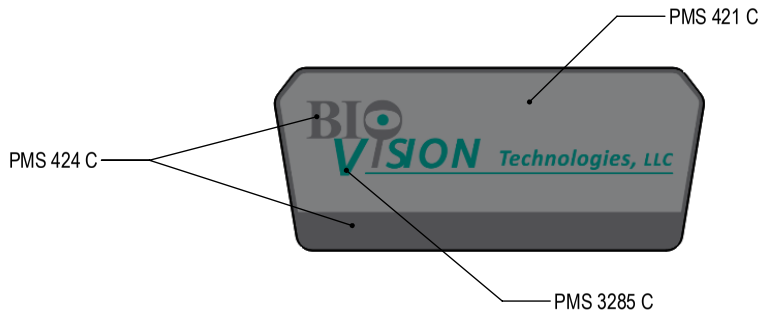
SIZE A | DWG. NO. **BVT51097-03001** | REV. X3B

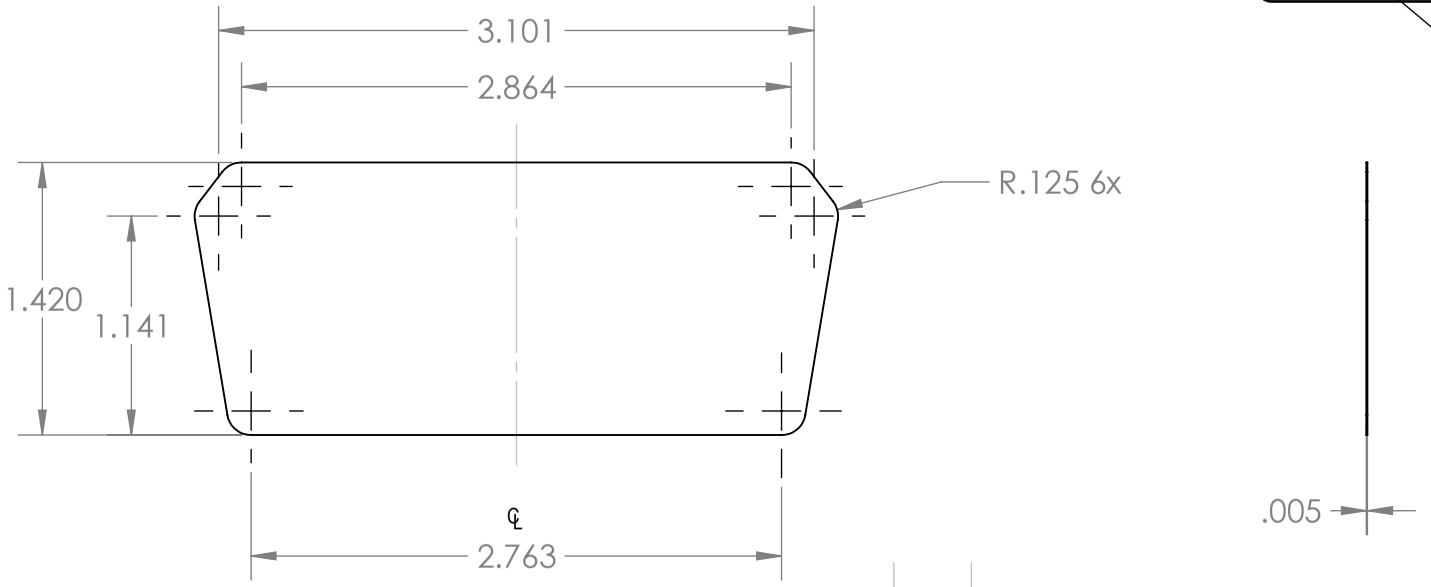
SCALE | SHEET 2 OF 2

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PART NO:
BVT51097-05101





NOTES:

1. Geometry to be controlled by CAD model: BVT51097-05101_Logo Label_Horrisontal Stand.sldprt and control dimensions.
2. Graphics to be controlled by CAD drawing: BVT51097-05101_Logo Label_Horrizontal Stand.ai
3. Base Color: White (Base), PMS 421
4. Additional colors: PMS 3285
5. Material: .005" Sabic, Lexan 8B35 Matte Textured, or approved equivalant
6. Addhesive: .005" 3M 468 MP, or approved equivalant

ECO #	Description	Date	REV.
X3B	Modified Material Specifications	11-07-2014	X3B

ENGINEERING CHANGE RECORD

UNLESS OTHERWISE SPECIFIED Dimension are in inches.
TOLERANCES ARE:
DECIMALS .XX: +/- .010 .XXX: +/- .005
ANGLES .XX: +/- 0.5 deg

MATERIAL: See Notes
FINISH: See Notes
DO NOT SCALE DRAWING

CAD GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS		DATE
MODELED	Pitzer	05-22-2013
DRAWN	Pitzer	11-07-2014
CHECKED	Korte	11-07-2014
RESP ENG	Sanso	11-07-2014
QUAL ENG	Ray	11-07-2014

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303-237-9608, Fax: 303-237-0757

Logo Label
Horrizontal Stand - BioVision

SIZE A | DWG. NO. BVT51097-05101 | REV. X3B
SCALE | SHEET 1 OF 2

BVT92100-04001 A.slddrt

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PART NO:
BVT51097-05101



SCALE 1.5 : 1

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ECO #	Description	Date	REV.

ENGINEERING CHANGE RECORD

UNLESS OTHERWISE SPECIFIED
Dimension are in inches.
TOLERANCES ARE:
DECIMALS: .XX: +/- .010, .XXX: +/- .005
ANGLES: .XX: +/- 0.5 deg

MATERIAL: See Notes

FINISH: See Notes

DO NOT SCALE DRAWING

CAD GENERATED DRAWING,
DO NOT MANUALLY UPDATE

APPROVALS		DATE
MODELED	Pitzer	05-22-2013
DRAWN	Pitzer	11-07-2014
CHECKED	Korte	11-07-2014
RESP ENG	Sanso	11-07-2014
QUAL ENG	Ray	11-07-2014

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Golden, CO 80401
303-237-9608, Fax: 303-237-0757

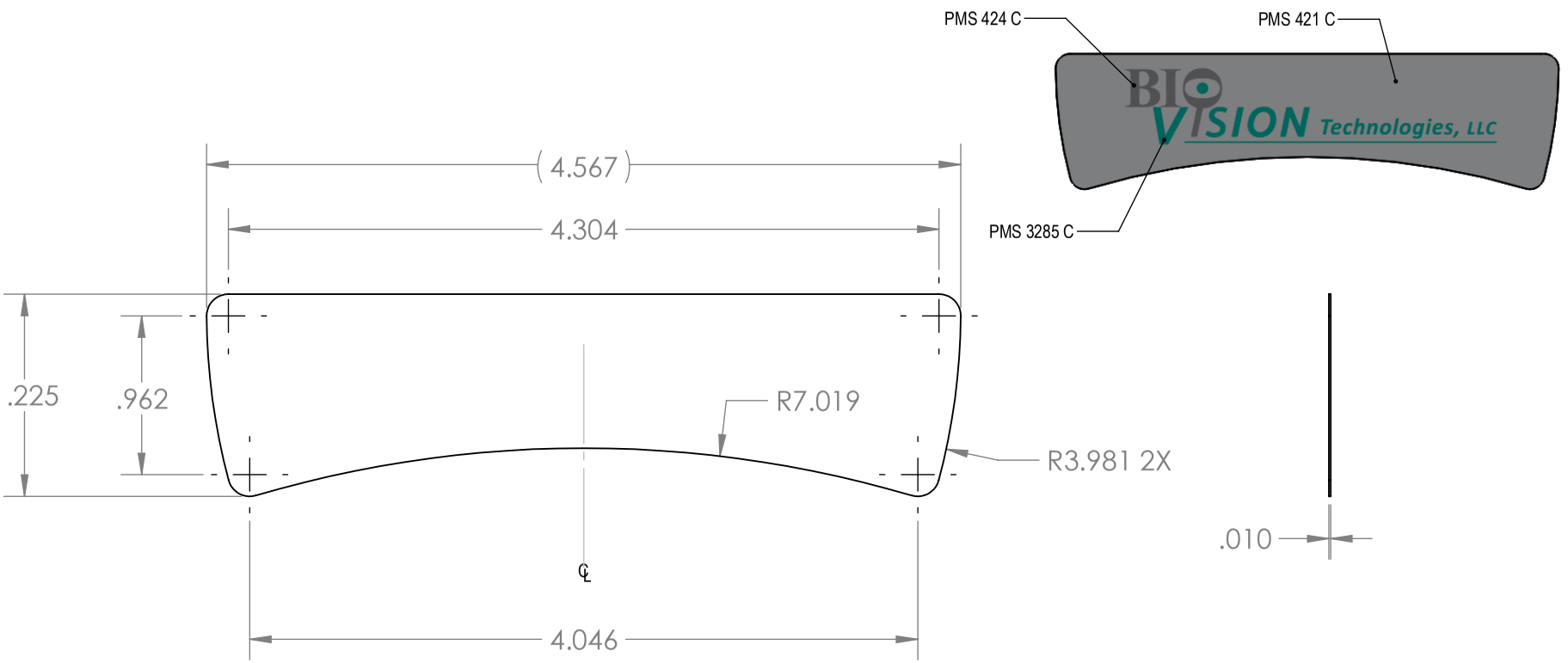
Logo Label
Horrizontal Stand - BioVision

SIZE: A
DWG. NO.: **BVT51097-05101**
REV.: X3B
SCALE:
SHEET 2 OF 2

BVT92100-04001 A.slddrt

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PART NO:
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NOTES:

1. Geometry to be controlled by CAD model: BVT51097-06001_Handpiece Cradle Label.sldprt and control dimensions.
2. Graphics to be controlled by CAD drawing: BVT51097-06001_Handpiece Cradle Label.ai
3. Base color: White (Base), PMS 421 C
4. Additional colors: PMS 424, PMS 3285,
5. Material: .010" Sabic, Lexan 8B35 Matte Textured, or approved equivalant
6. Addhesive: .005" 3M 468 MP, or approved equivalant

ECO #	Description	Date	REV.
X3B	Modified Material Specifications	11-07-2014	X3B

ENGINEERING CHANGE RECORD

UNLESS OTHERWISE SPECIFIED Dimension are in inches.
TOLERANCES ARE:
DECIMALS .XX: +/- .010 .XXX: +/- .005
ANGLES .XX: +/- 0.5 deg

MATERIAL: See Notes
FINISH: See Notes
DO NOT SCALE DRAWING

CAD GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS		DATE
MODELED	Pitzer	05-22-2013
DRAWN	Pitzer	11-07-2014
CHECKED	Korte	11-07-2014
RESP ENG	Sanso	11-07-2014
QUAL ENG	Ray	11-07-2014

BIO VISION Technologies, LLC.
221 Corporate Circle, Suite H
Golden, CO 80401
303-237-9608, Fax: 303-237-0757

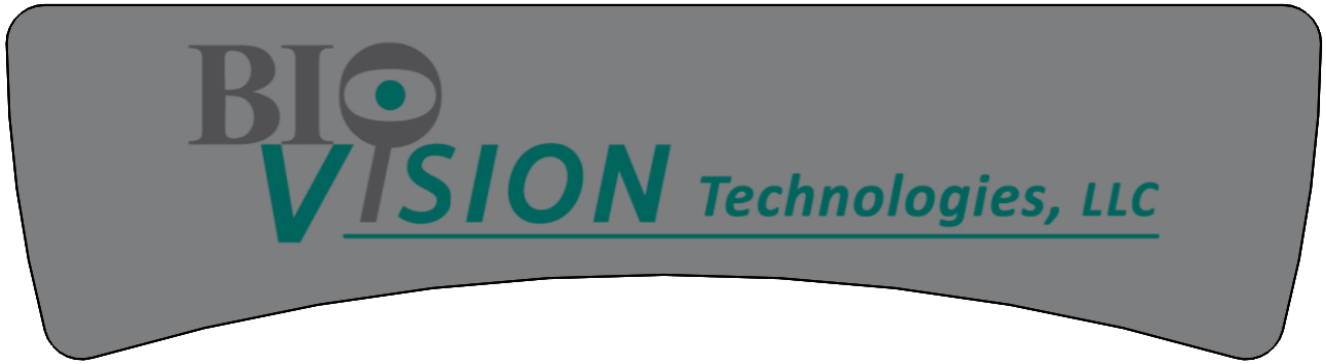
Handpiece Cradle Label
NeedleCam HD - BioVision

SIZE A | DWG. NO. BVT51097-06001 | REV. X3B
SCALE | SHEET 1 OF 2

BVT92100-04001 A.slddrt

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PART NO:
BVT51097-06001



SCALE 1.5 : 1

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ECO #	Description	Date	REV.

ENGINEERING CHANGE RECORD

UNLESS OTHERWISE SPECIFIED
Dimension are in inches.
TOLERANCES ARE:
DECIMALS .XX: +/- .010 .XXX: +/- .005
ANGLES .XX: +/- 0.5 deg

MATERIAL: See Notes

FINISH: See Notes

DO NOT SCALE DRAWING

CAD GENERATED DRAWING,
DO NOT MANUALLY UPDATE

APPROVALS		DATE
MODELED	Pitzer	05-22-2013
DRAWN	Pitzer	11-07-2014
CHECKED	Korte	11-07-2014
RESP ENG	Sanso	11-07-2014
QUAL ENG	Ray	11-07-2014

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Handpiece Cradle Label

NeedleCam HD - BioVision

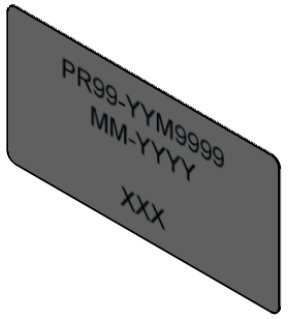
SIZE A | DWG. NO. BVT51097-06001 | REV. X3B

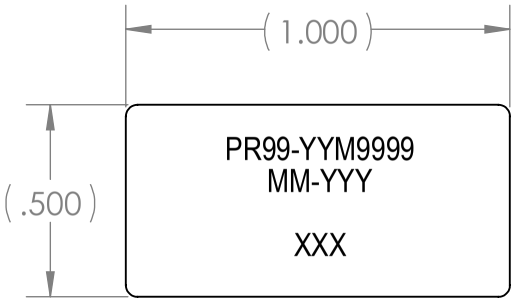
SCALE | SHEET 2 OF 2

BVT92100-04001 A.slddrt

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PART NO:
BVT51897-01001





NOTES:

1. ***LABEL MATERIAL: SILVER POLYESTER LABEL, THERMAL TRANSFER, P/N BVT***
2. ***PRINT USING THERMAL TRANSFER PRINTER (BRADY P/N TLS 2200) AND NO-SMEAR BLACK RIBBON (BRADY P/N 42011) OR EQUIVALENT.***
3. ***SERIAL NUMBER DESIGNATION: PR-YY-M-9999 WHERE "PR" IS THE PROJECT DESIGNATION, "YY" IS THE YEAR DESIGNATION, "M" IS THE MONTH DESIGNATION, AND "9999" IS A 4-DIGIT SEQUENTIAL NUMBER.***
4. ***Font type: ARIAL NARROW, Bold face, 6 pts.***

Materials List

Item #	BioVision P/N	ITEM DESCRIPTION	QTY	UOM
1	BVT51700-17435	Brady PTL-17-435, 1.00 in X 0.50 in, Silver	1	ea
2	BVT51700-04310	Brady R4310, Black Ribbon	0.02	in

ECO #	Description	Date	REV.

ENGINEERING CHANGE RECORD

UNLESS OTHERWISE SPECIFIED Dimension are in inches.
TOLERANCES ARE:
DECIMALS .XX: +/- .010 .XXX: +/- .005
ANGLES .XX: +/- 0.5 deg

MATERIAL N/A

FINISH N/A

DO NOT SCALE DRAWING

CAD GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS		DATE
MODELED	Pitzer	12-11-2014
DRAWN	Pitzer	12-11-2014
CHECKED	Korte	12-11-2014
RESP ENG	Sanso	12-11-2014
QUAL ENG	Ray	12-11-2014

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303-237-9608, Fax: 303-237-0757

NeedleCam HD Serial Label

SIZE A | DWG. NO. BVT51897-01001 | REV. X3

SCALE | SHEET 1 OF 1

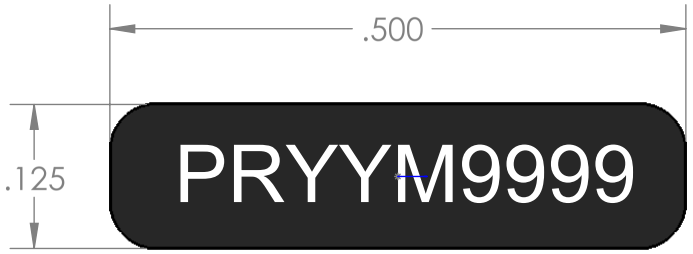
BVT92100-04001 A.slddrt

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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PART NO:
BVT51897-03002



NOTES:

1. ***LABEL MATERIAL: BLACK POLYESTER LABEL, THERMAL TRANSFER, P/N BVT89500-96181***
2. ***PRINT USING THERMAL TRANSFER PRINTER (BRADY P/N TLS 2200) AND NO-SMEAR WHITE RIBBON (BRADY P/N R4410-WT) OR EQUIVALENT.***
3. ***SERIAL NUMBER DESIGNATION: PR-YY-M-9999 WHERE "PR" IS THE PROJECT DESIGNATION, "YY" IS THE YEAR DESIGNATION, "M" IS THE MONTH DESIGNATION, AND "9999" IS A 4-DIGIT SEQUENTIAL NUMBER.***
4. ***Font type: ARIAL NARROW, Bold face, 6 pts.***

ECO #	DESCRIPTION	DATE	REV.

ENGINEERING CHANGE RECORD

UNLESS OTHERWISE SPECIFIED Dimension are in inches.
TOLERANCES ARE:
DECIMALS .XX: +/- .010 .XXX: +/- .005
ANGLES .XX: +/- 0.5 deg

MATERIAL: SEE NOTES
FINISH: NONE
DO NOT SCALE DRAWING

CAD GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS		DATE
MODELED	Pitzer	12-02-2014
DRAWN	Pitzer	12-02-2014
CHECKED	Korte	12-02-2014
RESP ENG	Sanso	12-02-2014
QUAL ENG	Ray	12-02-2014

BIO VISION Technologies, LLC.
221 Corporate Circle, Suite H
Golden, CO 80401
303-237-9608, Fax: 303-237-0757

Handpiece_Serial Label

SIZE A | DWG. NO. BVT51897-03002 | REV. X3
SCALE | SHEET 1 OF 1

BVT92100-04001 A.slddrt

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BIO VISION Technologies, LLC

NeedleCam HD

Contents - BVT01197-00001 - NeedleCam HD System

- NeedleCam HD S/N:_____
- Handpiece S/N:_____
- Manual
- Power Supply

TRANSPORT AND STORAGE

Ambient Temperature: 0°C to 50°C

Relative Humidity: 0% to 90%

Altitude: -1000ft to 12000ft

BioVision Technologies LLC
221 Corporate Circle
Suite H
Golden, Colorado USA
303.237.9608
biovisiontech.com

ntact FDA/CDRH/OCE/DID at CDRH-STATUS@fda.hhs.gov or call

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OnPoint System

Contents - BMT01197-00001 - OnPoint System

- ☐ - OnPoint System S/N:_____
- ☐ - Handpiece S/N:_____
- ☐ - Manual
- ☐ - Power Supply

TRANSPORT AND STORAGE

Ambient Temperature: 0°C to 50°C

Relative Humidity: 0% to 90%

Altitude: -1000ft to 12000ft

BioVision Technologies LLC
221 Corporate Circle
Suite H
Golden, Colorado USA
303.237.9608
biovisiontech.com

BVT89987-00001-A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Summary of Design Control Activities

The NeedleCam HD Visualization system was designed in accordance with BioVision Technologies design procedures. Risk analysis was completed in accordance with ISO 14971:2007, Medical Devices – Application of Risk Management to Medical Devices. The risk analysis method used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA). The design verification tests that were performed as a result of this risk analysis assessment are listed in Table 1 below. The test methods used are the same as those submitted in the original submission.

TABLE 1 – Verification / Validation Tests

Modification	Test Performed	Acceptance Criteria
Update image capture box	Safety Testing	Pass ANSI/AAMI ES60601-1:2005 (3rd edition) testing.
Update image capture system to USB storage device.	Software validation	The image must be captured on a USB drive.
Update the existing video format to the current digital format.	UL Safety Testing and Software validation	Validated to work with HDMI and component output.
Camera handpiece must be compatible with current SurgView Visualization System scopes.	Performance Testing	Existing scopes will couple with the updated handpiece.
Update system to LED light source.	Performance Testing	Light output of the camera must be at least 15 lumens.

Declaration of Conformity with Design Controls

Verification / Validation Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

David Sanso
President, BioVision Technologies
December 22, 2014

Manufacturing Facility

The manufacturing facility, *BioVision Technologies, LLC.* is in conformance with the design control requirements as specified in 21 CFR 820. 30 and the records are available for review.

Bonnie Ray
Quality Manager, BioVision Technologies
December 22, 2014

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-10065; Released by CDRH on 09-26-2016.

CERTIFICATE OF COMPLIANCE

Certificate Number 20141209-E467208
Report Reference E467208-A1-UL
Issue Date 2014-DECEMBER-09

Issued to: BIOVISION TECHNOLOGIES L L C
SUITE H
221 CORPORATE CIRCLE
GOLDEN CO 80401

This is to certify that representative samples of GENERAL MEDICAL EQUIPMENT
See Addendum Page

Have been investigated by UL in accordance with the Standard(s) indicated on this Certificate.

Standard(s) for Safety: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008), Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

Additional Information: See the UL Online Certifications Directory at www.ul.com/database for additional information

Only those products bearing the UL Certification Mark should be considered as being covered by UL's Certification and Follow-Up Service.

Look for the UL Certification Mark on the product.

Bruce Mahrenholz, Assistant Chief Engineer, Global Inspection and Field Services

UL LLC

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CERTIFICATE OF COMPLIANCE

Certificate Number 20141209-E467208
Report Reference E467208-A1-UL
Issue Date 2014-DECEMBER-09

This is to certify that representative samples of the product as specified on this certificate were tested according to the current UL requirements.

Endoscope Camera, Model 1080L
consists of BVT01097-00001 (NeedleCam HD base unit, cradle and stand and BVT01097-03001 NeedleCam Handpiece) or
LUT01097-00001 (NeedleCam HD base unit, cradle and stand - color specific for Lutronic)
LUT01097-03001 (NeedleCam Handpiece - color specific for Lutronic) or
BMT01097-00001 (NeedleCam HD base unit, cradle and stand - color specific for Biomet)
BMT01097-03001 (NeedleCam Handpiece - color specific for Biomet))

Bruce Mahrenholz, Assistant Chief Engineer, Global Inspection and Field Services

UL LLC

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UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)(Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance)
Certification Type:	Classification
CCN:	MDAF, MDAF7 (Medical Equipment - General Medical Equipment)
Product:	Endoscope Camera
Model:	Model 1080L (consists of BVT01097-00001 NeedleCam HD base unit, cradle and stand and BVT01097-03001 NeedleCam Handpiece or LUT01097-00001 (NeedleCam HD base unit, cradle and stand - color specific for Lutronic) LUT01097-03001 (NeedleCam Handpiece - color specific for Lutronic) or BMT01097-00001 (NeedleCam HD base unit, cradle and stand - color specific for Biomet) BMT01097-03001 (NeedleCam Handpiece - color specific for Biomet))
Rating:	100-240Vac, 50-60 Hz, 1.5A.
Applicant Name and Address:	BIOVISION TECHNOLOGIES L L C SUITE H 221 CORPORATE CIRCLE GOLDEN CO 80401 UNITED STATES

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of UL LLC ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

The applicant is authorized to reproduce the referenced Test Report provided it is reproduced in its entirety.

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Prepared by: Silvia Ankova Reviewed by: Paul Hilgeman

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Supporting Documentation

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

A. Authorization - The Authorization page may include additional Factory Identification Code markings.

B. Generic Inspection Instructions -

i. Part AC details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.

ii. Part AE details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.

iii. Part AF details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Product Description

The Biovision Technologies NeedleCam HD™ Integrated Visualization System is indicated to provide illumination and visualization of anatomy in an interior cavity of the body through a natural or surgical opening. The handpiece is covered by a sterile drape.

Model Differences

All models NeedleCam HD base unit, cradle and stand and NeedleCam Handpiece are identical except the color for different customers.

Technical Considerations

- Classification of installation and use : Portable
- Device type (component/sub-assembly/ equipment/ system) : Equipment
- Intended use (Including type of patient, application location) : provide illumination and visualization of anatomy in an interior cavity of the body through a natural or surgical opening
- Mode of operation : Continuous
- Supply connection : Appliance coupler
- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards:: EN 60601-1: 2006 + CORR: 2010 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance), CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada), ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States), IEC 60601-2-18 MEDICAL ELECTRICAL EQUIPMENT. PT. 2-18, PARTICULAR REQUIREMENTS FOR SAFETY OF ENDOSCOPIC EQUIPMENT - Edition 3 - Issue Date 2009/08/01, KS C IEC 60601-1:2009, IEC 60601-1-2 (2007)
- The product was not investigated to the following standards or clauses:: Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)
- The degree of protection against harmful ingress of water is:: Ordinary
- The mode of operation is:: Continuous
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide:: No

Additional Information

N/A

Markings and instructions

Clause Title	Marking or Instruction Details
Company identification	Classified or Recognized company's name, Trade name, Trademark or File
Model	Model number
Supply Connection	Voltage range, ac/dc, phases if more than single phase

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Alternating current	
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts
Type BF applied part	
Special Instructions to UL Representative Dielectric test to be conducted on 100% of the hand piece cords 1000V for 1 min during the inspection.	

Production-Line Testing Requirements			
Test Exemptions - The following models are exempt from the indicated test			
Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand
1080L	1080L exempt	1080L exempt	1080L exempt
Solid-State Component Test Exemptions - The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:			
Component			
N/A			
Sample and Test Specifics for Follow-Up Tests at UL			
The following tests shall be conducted in accordance with the Generic Inspection Instructions			
Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
N/A			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Enclosures

Type	Supplement Id	Description
Collateral	11-01	IEC 60601-1-2
Particular	12-01	IEC 60601-2-18
Photographs	3-01	inside view
Photographs	3-02	hand piece metal sliding sleeve
Photographs	3-03	outside view
Photographs	3-04	hand piece with plastic sliding sleeve
Manuals	6-01	Manual
Miscellaneous	7-01	label
Miscellaneous	7-02	hand piece label
Miscellaneous	7-03	Strain relief drawing
Miscellaneous	7-05	hand piece cord
Miscellaneous	7-06	NeedleView Scope
Miscellaneous	7-07	NeedleView CH Scope
Miscellaneous	7-09	Korean national differences
Miscellaneous	7-10	hand piece sliding sleeve

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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BioVision NeedleCam HD™ Software Validation Report

Document Number:

BVT96097-00013

BioVision Technologies Approvals:

Engineering: _____ Date: 12-19-14

Quality: Bonnie Ray Date: 12/19/14

Operations: _____ Date: 12-19-14

The Realtime Group Approvals:

Engineering: James R. Hacker Date: 12/19/14

Quality: _____ Date: 19-Dec-14

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1 Introduction

1.1 Purpose

This document assesses the validation status of the NeedleCam HD Software.

1.2 Scope

The software on which this validation report is conducted is labeled as Revision 1.0L.

1.3 Associated Documents

The following documents are referenced within this specification.

1.3.1 Internal Specifications

Doc # and Revision	Title
BVT96097-00007, Rev B	BioVision NeedleCam HD System / Software Safety Test Protocol
BVT96097-00002, Rev B	BioVision NeedleCam HD Software Requirements Specification (SRS)
BVT96097-00011, Rev A	BioVision NeedleCam HD Software Architecture Documentation
BVT96097-00010, Rev A	NeedleCam HD SOUP Analysis
BVT96097-00004, Rev A	BioVision NeedleCam Software 1.0L Version Description Document
BVT94397-00004, Rev A1	BioVision NeedleCam HD Hazard Analysis
BVT94397-00005, Rev A1	BioVision NeedleCam HD DFMEA
BVT96097-00008, Rev B	BioVision NeedleCam HD System / Software Safety Test Report

1.3.2 External Documents

Identification
General Principles of Software Validation; Final Guidance for Industry and FDA Staff, 11-Jan-2002
ANSI/AAMI/IEC 62304:2006, Medical device software - Software life cycle processes

1.4 Definitions and Acronyms

Label	Definition
COTS	Commercial Off The Shelf
POST	Power On Self-Test
SOUP	Software Of Unknown Provenance/Pedigree
SRS	Software Requirements Specification

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2 Software Documentation

The software is fully specified in the BioVision NeedleCam HD Software Requirements Specification (SRS). The SRS contains a summary overview of the features and software operating environment.

Risks, including those regarding the software are identified in the BioVision NeedleCam HD Hazard Analysis and BioVision NeedleCam HD DFMEA documents.

An architecture document was prepared to provide a top-level view of the system. The architecture documentation is BioVision NeedleCam HD Software Architecture Document.

A design document was prepared to provide details describing the software design. The design documentation is in BioVision NeedleCam Software Design Description.

The release is fully described in the BioVision NeedleCam Software 1.0L Version Description Document.

3 Software Analysis

A software analysis was conducted to provide an independent assessment of the software. The LINT program was run, a review of the LINT findings was conducted, and a manual code inspection was conducted. The findings from these efforts are documented in the R1.0L Code Inspection report. Based on the report, the analysis concludes that the software

The SOUP / COTS incorporated has been fully identified and assessed and has been confirmed to:

- ✓ Be used in a manner consistent with the intention of the provider
- ✓ Do not have known issues that would limit or impact use of the system
- ✓ Is adequately controlled through the configuration management system

The software analysis confirms the basic design of the system is sound and can support future enhancements, as needed.

4 Software Verification Test Results

The software requirements defined in Revision B of the BioVision NeedleCam HD Software Requirements Specification (SRS) were verified through executing the BioVision NeedleCam HD System / Software Safety Test Protocol. Results have been documented in the BioVision NeedleCam HD System / Software Safety Test Report, revision B.

All requirements in the SRS revision B were verified.

There are no known issues with the software in typical use conditions that would cause a failure for the operator or result in loss of data / loss of data integrity.

5 Process

Software release version 1.0L is baselined and under BioVision change / configuration control.

The software is sufficiently specified through requirements established in BioVision NeedleCam HD Software Requirements Specification (SRS) revision B. The requirements were reviewed to ensure completeness, consistency, and cohesiveness. The document is under BioVision Document Control and any subsequent changes would be made through Design Change controls.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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The development environment is fully defined and documented in the BioVision NeedleCam Software Design Description.

The process to install new software is fully defined and automated. No work instructions are necessary since the process is fully automated and successful installation is confirmed.

The change control process is in place, functioning, and enables proper change tracking and configuration identification.

6 Validation Assessment

Based on the results of the software analysis, verification results, and the assessment of the processes, the software is considered **validated** and can be released for distribution.

7 Document Revision History

Rev	Revision Description	Author	Date	ECO
A	Initial Release	D.Hurd	12/19/2014	2538

It is the responsibility of the user to verify that this copy is of the latest revision. This document is maintained on electronic media, the current revision of this document is located on BioVision Technologies' network.

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(b)(4) Confidential and Proprietary Information - Testing

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Statement re: Sterilization, Biocompatibility and Expiration Date

Sterilization

Sterilization validation was not completed for the NeedleCam HD device. The device is sold non-sterile.

Biocompatibility

Biocompatibility testing was not completed for the NeedleCam HD device. The device is not patient contact. Biocompatibility testing was completed on the scopes which are used with the NeedleCam HD device. The testing for the scopes were submitted for the original submission and have not changed.

Expiration Date

There is no expiration date for the NeedleCam HD device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-10065; Released by CDRH on 09-26-2016.

BIO VISION Technologies, LLC Visualizing Better Care

221 Corporate Circle, Suite H
Golden, Colorado 80401 USA
Phone: 303-237-9608 • Fax: 303-237-0757
www.biovisiontech.com

SPECIAL 510(K) NOTIFICATION Cover Letter

K143705|S001

510(k) Number	**K143705**
Date:	**January 29, 2015**
Applicant:	BioVision Technologies, L.L.C.
Address:	221 Corporate Circle Unit H Golden, Colorado 80401
Contact Person:	David Sanso President (303) 237-9608
Type of Submission:	**Special 510(K)**
Propriety Name:	NeedleCam HD™ Visualization System
Regulation Name:	Arthroscope/Endoscope
Classification Regulation:	21 CFR §888.1100, 21 CFR 876.1500
Classification Name:	Arthroscope / Endoscope and Accessories
Regulatory Class:	II
Prior Submissions:	There have been no prior submissions for this device
Continued Confidentiality:	BioVision Technologies agrees to the confidentiality agreement outlined in 21 CFR §807.95.
FDA Panel:	87 / 78
Product Code:	HRX/GCJ

FDA CDRH DMC
JAN 30 2015
Received

Purpose: The purpose of this Special 510(k) submission is the response to the deficiency letter received on January 21, 2015.

eCopy Statement: The eCopy is an exact duplicate of the paper copy.

Submitters Signature:

David Sanso, President

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-10065; Released by CDRH on 09-26-2016.

K143705/S1

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FDA CDRH DMC
JAN 29 2015
Received

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Address:	221 Corporate Circle Unit H Golden, Colorado 80401
Contact Person:	David Sanso President (303) 237-9608
Type of Submission:	**Special 510(K)**
Propriety Name:	NeedleCam HD™ Visualization System
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Classification Regulation:	21 CFR §888.1100, 21 CFR 876.1500
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David Sanso, President

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January 26, 2015

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

Re: K143705 – 1st Deficiency Letter

A request from the FDA was received via email on January 21, 2015 for the following deficiency questions. BioVision Technologies offers the following response:

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-10065; Released by CDRH on 09-26-2016.

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-2OISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-3OISTATUS@fda.hhs.gov or call 301-796-8118.

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If you have further questions, please contact David Sanso at 303-478-2018 or Bonnie Ray at 303-237-9608.

Sincerely,

Bonnie Ray
Quality Manager, BioVision Technologies

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Verification and Validation Plan

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Records processed under FOIA Request #2015-10065; Released by CDRH on 09-26-2016.

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221 Corporate Circle, Suite H
Golden, Colorado 80401 USA
Phone: 303-237-9608 • Fax: 303-237-0757
www.biovisiontech.com

Needle Cam HD™ Visualization System
Special 510(k) Submission

SPECIAL 510(k) SUMMARY

Submission Information

Date Prepared: December 22, 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: NeedleCam HD™ Visualization System

Common Name: Arthroscope/Endoscope

Classification Name: Arthroscope / Endoscope and Accessories

Regulation Number: 21 CFR §888.1100, HRX

21 CFR §876.1500, GCJ

Regulatory Class: II

Predicate Device

BioVision Technologies SurgView™ Integrated Visualization System (K082293)

Device Description

Name of the Device: NeedleCam HD™ Visualization System

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-10065; Released by CDRH on 09-26-2016.

NeedleCam HD™ Visualization System is comprised of an Image Capture Box, a Camera Handpiece (including an LED light source) that captures still images and full resolution video, and External Power Supply. The camera has a quick-release optical connector that adapts to a wide variety of Bio Vision Technologies' surgical endoscopes. The device is used with an endoscope to visualize and illuminate an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures.

The BioVision endoscopes and supplemental instruments that were approved with the predicate SurgView Visualization System have not been changed.

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.

NeedleCam HD System Components and Accessories

The NeedleCam HD Visualization System is intended to be used with BioVision endoscopes. The following is a listing of the current compatible scopes, along with the applicable 510(k) clearance numbers.

Part Number	Description	510(k) Number
BVTKIT72-0L065	OnPoint 0 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-0L165	BioVision NeedleView 0 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-0L1A0	BioVision NeedleView 0 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R165	BioVision NeedleView 10 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R1A0	BioVision NeedleView 10 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R265	InnerVue II 10 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R2A0	InnerVue II 10 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293

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BVTKIT75-3R165	BioVision NeedleView 30 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT75-3R1A0	BioVision NeedleView 30 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT82-34001	BioVision NeedleView CH 3.4mm Scope Kit (including scope, cannula, dilator, tuohy needles, scalpel and guidewire	K141326

Comparison to Predicate Device

The table below shows relevant similarities and differences between the NeedleCam HD™ Visualization System and its predicate device – SurgView™ Integrated Visualization System (K082293).

APPLICANT DEVICE: NeedleCam HD™ Visualization System

PREDICATE DEVICE: SurgView™ Visualization System (K082293)

NOTE: **Relevant similarities are identified in bold text.**
Relevant differences are identified in underlined text.

PREDICATE COMPARISON CHART

I. GENERAL CHARACTERISTICS			PREDICATE DEVICE
ITEM	**FEATURE**	**NeedleCam HD Visualization System**	**SurgView™ Visualization System K082293**
1	**Device Description**	NeedleCam HD Visualization System **is a video endoscope/arthroscope imaging system consisting of the following components:** 1. **An Image Capture Box that includes image processor and** external power supply) 2. **Camera handpiece** including a LED light source. 3. **A semi-rigid Fiberoptic Scope in a variety of diameters, lengths, and viewing angles. Supplemental instruments include a cannula, trocar, obturator, and cannula plug.** 4. Media Capture USB System 5. **Video Outputs for external monitor**	The SurgView™ Visualization System **is a video endoscope/arthroscope imaging system consisting of the following components:** 1. **A Light Source/Display/Image Capture device that includes** an internal monitor, **image processor,** Xenon light source and internal power supply**.** 2. **Camera handpiece**. 3. **A semi-rigid Fiberoptic Scope in a variety of diameters, lengths, and viewing angles. Supplemental instruments for the scope include a cannula, trocar, obturator, and cannula plug.** 4. Media Capture CF Card System 5. **Video output for external monitor.**

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2	Intended Use	Needle Cam HD™ **Visualization 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, shoulder, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and cervix**.	The SurgView™ **Visualization 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, shoulder, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and cervix**.
3	Materials Used	**Plastic enclosure, media capture board**, **plastic camera cable.** **Scopes & instruments - Stainless Steel for Scope Shaft; Fiber Optics for light transmission**	**Plastic enclosure,** metal plate, **media capture board**, **plastic camera cable**, and fiber optic cable**.** **Scopes & instruments - Stainless Steel for Scope Shaft; Fiber Optics for light transmission**
4	Labeling (Single Use/Reusable)	**Image capture box and camera handpiece: Reusable.** **Scopes & instruments: Sterile, Single Use**	**Image capture box and camera handpiece: Reusable.** **Scopes & instruments: Sterile, Single Use**
5	Image acquisition	**Image acquisition is achieved through an endoscope attached to a camera handpiece. The endoscope is in the sterile field while the handpiece remains non-sterile. A barrier is provided to preserve the sterile field.**	**Image acquisition is achieved through an endoscope attached to a camera handpiece. The endoscope is in the sterile field while the handpiece remains non-sterile. A barrier is provided to preserve the sterile field.**
6	Connectivity	**The endoscope, camera handpiece, cable, illumination source and image processor connections allow functional coupling of the components while providing safe and reliable connections, in particular those related to electrical safety for the user and patient. The endoscope attached to the camera handpiece using a quick release connection.** The LED light source is included in the camera handpiece. **The camera cable connects to the image capture device using a single electrical connector.**	**The endoscope, camera handpiece, cable, illumination source and image processor connections allow functional coupling of the components while providing safe and reliable connections, in particular those related to electrical safety for the user and patient. The endoscope attached to the camera handpiece using a quick release connection.** The fiberoptic bundle is integrated with the camera cable. **The camera cable connects to the** light source**/image capture device using a single hybrid (electrical/optical) connector.**
7	Image processing	**The image is digitally processed to allow further manipulation, capture, printing, and multiple displays.**	**The image is digitally processed to allow further manipulation, capture, printing, and multiple displays.**
8	Image display (s)	**External monitor connection**	Internal monitor display with **external monitor connection.**
9	Data Entry	**Session information entered via external keyboard**	**Session information entered via external keyboard**

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10	Data storage	Image and video storage to USB device	Image and video storage to Compact Flash™ cards.
11	Where used	**Hospital / Doctor's office**	**Hospital / Doctor's office**
II. CHARACTERISTICS OF THE LIGHT SOURCE			
ITEM	FEATURE	**NeedleCam HD™ Visualization System**	**SurgView™ Visualization System K082293**
1	Illumination	**Illumination is achieved via** an internal LED light source. **The** LED **light source is an integral part of the device.** The LED is internal to the camera handpiece. **LED and Xenon usable light output is equivalent.**	**Illumination is achieved via** a fiberoptic bundle attached to the endoscope**. The** Xenon **light source is an integral part of the device.** The Xenon light source is internal to the image capture box. **LED and Xenon usable light output is equivalent.**
2	Type of light source	LED	Xenon
3	Lamp power rating	1W	35W
4	Rated lamp life	20,000 hours	3,000 hours
5	Luminous intensity as measured at scope output	**4-6 lumens**	**4-6 lumens**
III. CHARACTERISTICS OF THE CAMERA			
ITEM	FEATURE	**NeedleCam HD™ Visualization System**	**SurgView™ Visualization System**
1	Camera sensor	**¼" CCD**	**¼" CCD**
2	Sensor resolution	**768(H) x 494(V) pixels**	**768(H) x 494(V) pixels**
3	Camera resolution	**480 lines, interlaced**	**480 lines, interlaced**
4	Camera sterility	**Non sterile. Drape is used for sterile field preservation.**	**Non sterile. Drape is used for sterile field preservation.**
5	Endoscope coupler	**Built-in**	**Built-in**

Conclusion: Based on the evaluation of the performance characteristics, construction, manufacturing processes, and indications of use, BioVision Technologies has concluded that the BioVision NeedleCam HD ™ Visualization System is substantially equivalent to the predicate device listed in this submission.

The upgrades were completed to incorporate the improved light source options provided by LED lighting. The industry standard for media storage has moved from CF cards to USB technology. Additionally, analog television technology has been replaced by digital television technology.

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Summary of Technologies

The technological characteristics of the BioVision NeedleCam HD™ Visualization System are similar to its predicate device – BioVision SurgView™ Visualization System (K082293). The indications and contraindications listed in this submission are in congruence between these devices. The modifications are incremental changes to the predicate image capture box and camera handpiece that do not affect safety and effectiveness of the modified device. The modifications are the following:

1) Update the image capture box to the current standard USB storage device;
2) Update the existing video format to the current digital format.
3) The camera handpiece has been upgraded with an LED light source.

We believe these modifications are eligible for the Special 510 (k) process since they have the same fundamental scientific technology and intended use as the predicate device.

Performance Testing

Establishment of equivalence is based on similarities of intended use, design, physical characteristics and geometry between the BioVision NeedleCam HD™ Visualization System and its predicate device – BioVision SurgView™ Visualization System (K082293).

Safety testing was completed to ANSI/AAMI ES 60601-1:2005 (3rd edition) on the BioVision NeedleCam HD™ Visualization System. Additionally software validation was completed on the system.

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 Needle Cam HD and its predicate device.

Conclusion

Based on the evaluation of the performance characteristics, construction, manufacturing processes, and indications of use, BioVision Technologies has concluded that the BioVision Needle Cam HD™ Visualization System is substantially equivalent to the predicate device listed above. In all cases, the characteristics of this device are identical or similar to the predicate device as they relate to the intended uses or application. BioVision Technologies has also determined that the modification is an incremental change to the existing device that does not affect safety and effectiveness of the device.

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Visualizing Better Care

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Needle Cam HD™ Visualization System
Special 510(k) Submission

SPECIAL 510(k) SUMMARY

Submission Information

Date Prepared: December 22, 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: NeedleCam HD™ Visualization System

Common Name: Arthroscope/Endoscope

Classification Name: Arthroscope / Endoscope and Accessories

Regulation Number: 21 CFR §888.1100, HRX

21 CFR §876.1500, GCJ

Regulatory Class: II

Predicate Device

BioVision Technologies SurgView™ Integrated Visualization System (K082293)

Device Description

Name of the Device: NeedleCam HD™ Visualization System

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NeedleCam HD™ Visualization System is comprised of an Image Capture Box, a Camera Handpiece (including an LED light source) that captures still images and full resolution video, and External Power Supply. The camera has a quick-release optical connector that adapts to a wide variety of Bio Vision Technologies' surgical endoscopes. The device is used with an endoscope to visualize and illuminate an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures.

The BioVision endoscopes and supplemental instruments that were approved with the predicate SurgView Visualization System have not been changed.

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.

NeedleCam HD System Components and Accessories

The NeedleCam HD Visualization System is intended to be used with BioVision endoscopes. The following is a listing of the current compatible scopes, along with the applicable 510(k) clearance numbers.

Part Number	Description	510(k) Number
BVTKIT72-0L065	OnPoint 0 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-0L165	BioVision NeedleView 0 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-0L1A0	BioVision NeedleView 0 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R165	BioVision NeedleView 10 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R1A0	BioVision NeedleView 10 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R265	InnerVue II 10 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R2A0	InnerVue II 10 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293

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BVTKIT75-3R165	BioVision NeedleView 30 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT75-3R1A0	BioVision NeedleView 30 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT82-34001	BioVision NeedleView CH 3.4mm Scope Kit (including scope, cannula, dilator, tuohy needles, scalpel and guidewire	K141326

Comparison to Predicate Device

The table below shows relevant similarities and differences between the NeedleCam HD™ Visualization System and its predicate device – SurgView™ Integrated Visualization System (K082293).

APPLICANT DEVICE: NeedleCam HD™ Visualization System

PREDICATE DEVICE: SurgView™ Visualization System (K082293)

NOTE: **Relevant similarities are identified in bold text.**
Relevant differences are identified in underlined text.

PREDICATE COMPARISON CHART

I. GENERAL CHARACTERISTICS			PREDICATE DEVICE
ITEM	**FEATURE**	**NeedleCam HD Visualization System**	**SurgView™ Visualization System K082293**
1	**Device Description**	NeedleCam HD Visualization System **is a video endoscope/arthroscope imaging system consisting of the following components:** 1. **An Image Capture Box that includes image processor and** external power supply) 2. **Camera handpiece** including a LED light source. 3. **A semi-rigid Fiberoptic Scope in a variety of diameters, lengths, and viewing angles. Supplemental instruments include a cannula, trocar, obturator, and cannula plug.** 4. Media Capture USB System 5. **Video Outputs for external monitor**	The SurgView™ Visualization System **is a video endoscope/arthroscope imaging system consisting of the following components:** 1. **A Light Source/Display/Image Capture device that includes** an internal monitor, **image processor,** Xenon light source and internal power supply**.** 2. **Camera handpiece**. 3. **A semi-rigid Fiberoptic Scope in a variety of diameters, lengths, and viewing angles. Supplemental instruments for the scope include a cannula, trocar, obturator, and cannula plug.** 4. Media Capture CF Card System 5. **Video output for external monitor.**

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2	Intended Use	Needle Cam HD™ **Visualization 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, shoulder, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and cervix**.	The SurgView™ **Visualization 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, shoulder, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and cervix**.
3	Materials Used	**Plastic enclosure, media capture board**, **plastic camera cable.** **Scopes & instruments - Stainless Steel for Scope Shaft; Fiber Optics for light transmission**	**Plastic enclosure,** metal plate, **media capture board**, **plastic camera cable**, and fiber optic cable**.** **Scopes & instruments - Stainless Steel for Scope Shaft; Fiber Optics for light transmission**
4	Labeling (Single Use/Reusable)	**Image capture box and camera handpiece: Reusable.** **Scopes & instruments: Sterile, Single Use**	**Image capture box and camera handpiece: Reusable.** **Scopes & instruments: Sterile, Single Use**
5	Image acquisition	**Image acquisition is achieved through an endoscope attached to a camera handpiece. The endoscope is in the sterile field while the handpiece remains non-sterile. A barrier is provided to preserve the sterile field.**	**Image acquisition is achieved through an endoscope attached to a camera handpiece. The endoscope is in the sterile field while the handpiece remains non-sterile. A barrier is provided to preserve the sterile field.**
6	Connectivity	**The endoscope, camera handpiece, cable, illumination source and image processor connections allow functional coupling of the components while providing safe and reliable connections, in particular those related to electrical safety for the user and patient. The endoscope attached to the camera handpiece using a quick release connection.** The LED light source is included in the camera handpiece. **The camera cable connects to the image capture device using a single electrical connector.**	**The endoscope, camera handpiece, cable, illumination source and image processor connections allow functional coupling of the components while providing safe and reliable connections, in particular those related to electrical safety for the user and patient. The endoscope attached to the camera handpiece using a quick release connection.** The fiberoptic bundle is integrated with the camera cable. **The camera cable connects to the** light source**/image capture device using a single hybrid (electrical/optical) connector.**
7	Image processing	**The image is digitally processed to allow further manipulation, capture, printing, and multiple displays.**	**The image is digitally processed to allow further manipulation, capture, printing, and multiple displays.**
8	Image display (s)	**External monitor connection**	Internal monitor display with **external monitor connection.**
9	Data Entry	**Session information entered via external keyboard**	**Session information entered via external keyboard**

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10	Data storage	Image and video storage to USB device	Image and video storage to Compact Flash™ cards.
11	Where used	**Hospital / Doctor's office**	**Hospital / Doctor's office**
II. CHARACTERISTICS OF THE LIGHT SOURCE			
ITEM	FEATURE	**NeedleCam HD™ Visualization System**	**SurgView™ Visualization System K082293**
1	Illumination	**Illumination is achieved via** an internal LED light source. **The** LED **light source is an integral part of the device.** The LED is internal to the camera handpiece. **LED and Xenon usable light output is equivalent.**	**Illumination is achieved via** a fiberoptic bundle attached to the endoscope**. The** Xenon **light source is an integral part of the device.** The Xenon light source is internal to the image capture box. **LED and Xenon usable light output is equivalent.**
2	Type of light source	LED	Xenon
3	Lamp power rating	1W	35W
4	Rated lamp life	20,000 hours	3,000 hours
5	Luminous intensity as measured at scope output	**4-6 lumens**	**4-6 lumens**
III. CHARACTERISTICS OF THE CAMERA			
ITEM	FEATURE	**NeedleCam HD™ Visualization System**	**SurgView™ Visualization System**
1	Camera sensor	**¼" CCD**	**¼" CCD**
2	Sensor resolution	**768(H) x 494(V) pixels**	**768(H) x 494(V) pixels**
3	Camera resolution	**480 lines, interlaced**	**480 lines, interlaced**
4	Camera sterility	**Non sterile. Drape is used for sterile field preservation.**	**Non sterile. Drape is used for sterile field preservation.**
5	Endoscope coupler	**Built-in**	**Built-in**

Conclusion: Based on the evaluation of the performance characteristics, construction, manufacturing processes, and indications of use, BioVision Technologies has concluded that the BioVision NeedleCam HD ™ Visualization System is substantially equivalent to the predicate device listed in this submission.

The upgrades were completed to incorporate the improved light source options provided by LED lighting. The industry standard for media storage has moved from CF cards to USB technology. Additionally, analog television technology has been replaced by digital television technology.

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Summary of Technologies

The technological characteristics of the BioVision NeedleCam HD™ Visualization System are similar to its predicate device – BioVision SurgView™ Visualization System (K082293). The indications and contraindications listed in this submission are in congruence between these devices. The modifications are incremental changes to the predicate image capture box and camera handpiece that do not affect safety and effectiveness of the modified device. The modifications are the following:

1) Update the image capture box to the current standard USB storage device;
2) Update the existing video format to the current digital format.
3) The camera handpiece has been upgraded with an LED light source.

We believe these modifications are eligible for the Special 510 (k) process since they have the same fundamental scientific technology and intended use as the predicate device.

Performance Testing

Establishment of equivalence is based on similarities of intended use, design, physical characteristics and geometry between the BioVision NeedleCam HD™ Visualization System and its predicate device – BioVision SurgView™ Visualization System (K082293).

Safety testing was completed to ANSI/AAMI ES 60601-1:2005 (3rd edition) on the BioVision NeedleCam HD™ Visualization System. Additionally software validation was completed on the system.

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 Needle Cam HD and its predicate device.

Conclusion

Based on the evaluation of the performance characteristics, construction, manufacturing processes, and indications of use, BioVision Technologies has concluded that the BioVision Needle Cam HD™ Visualization System is substantially equivalent to the predicate device listed above. In all cases, the characteristics of this device are identical or similar to the predicate device as they relate to the intended uses or application. BioVision Technologies has also determined that the modification is an incremental change to the existing device that does not affect safety and effectiveness of the device.

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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

K143705
BioVision Technologies, LLC
NeedleCam HD Visualization System

Please address the following deficiency questions:

(b)(4) Confidential and Proprietary Information

[redacted]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143705

Device Name
NeedleCam HD™ Visualization System

Indications for Use *(Describe)*
NeedleCam HD™ Visualization System

Indications for Use: The NeedleCam HD™ Visualization 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.

This is the same intended use as for a previously cleared device - the BioVision Technologies SurgView™ Integrated Visualization System (K082293).

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143705

Device Name
NeedleCam HD™ Visualization System

Indications for Use *(Describe)*
NeedleCam HD™ Visualization System

Indications for Use: The NeedleCam HD™ Visualization 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.

This is the same intended use as for a previously cleared device - the BioVision Technologies SurgView™ Integrated Visualization System (K082293).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE RE: DOCUMENT NUMBER K143705

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

This change was for:

(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information

[redacted]

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	Yes	No	
(Identify the new device and the predicate device) 1. Is the predicate device legally marketed?			If **YES** = Go To 2 If **NO** = Stop **NSE**
(Review all labeling and assure that it is consistent with IFU statements) 2. Do the devices have the same intended use?			If **YES** = Go to 3, Respond to "A." below If **NO** = Stop **NSE**, Respond to "A." below
(Review design, materials, energy source and other features of the devices) 3. Do the devices have the same technological characteristics?			If **YES** = Stop If **NO** = Go to 4, Respond to "B." below
(Determine what questions of safety and effectiveness the different technological characteristics raise) 4. Do the different technological characteristics of the devices raise different questions of safety and effectiveness?			If **YES** = Stop **NSE**, Respond to "C." below If **NO** = Go to 5
(Review the proposed scientific methods for evaluating new/ different characteristics' effects on safety and effectiveness) 5a. Are the methods acceptable?			If **YES** = Go to 5b If **NO** = Stop N**SE**, Respond to "D." below
(Evaluate performance data) 5b. Do the data demonstrate substantial equivalence?			If **YES** = Stop **SE,** Respond to "E." below If **NO** = Stop N**SE**, Respond to "E." below

Note: Please complete the following table and answer the corresponding questions.

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A. Please explain how the intended use of the subject device is similar to or different from the predicate device.

B. Please describe the different technological characteristics.

C. Please explain how the technological characteristics raise different questions of safety and effectiveness.

D. Please explain why the proposed scientific method for evaluating new/ different characteristics' effects on safety and effectiveness are not acceptable.

E. Please explain how the data do or do not demonstrate substantial equivalence.

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off (optional)	
Division Sign-Off (optional)	

Revised: 8/1/03
10/16/2012 – MMJ placed in Digital Signature format
1/28/13; GKP: Division digital signature optional
2/7/2013 – MMJ: BC signature optional. Per Barb's latest update (2/6/13), review memos and checklists only need to be digitally signed by the reviewer. No other signatures are required. The logging out of a document in CTS and, when applicable, the signing of the letter, is considered an appropriate and sufficient indicator that the review memo or checklist was reviewed by each level of management.
6/5/14: ERJ removed Sections 5c and 6 per Patrick Axtell
9/9/14:FXR replaced the SE decision table to be aligned with the new 510(k) guidance document
9/18/2014: FXR revised the SE decision table, question #4.

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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

February 20, 2015

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

Re: K143705
Trade/Device Name: NeedleCam HD™ Visualization System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, GCJ
Dated: January 29, 2015
Received: January 30, 2015

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. 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

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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.

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Sincerely yours,

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

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February 20, 2015

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

Re: K143705
Trade/Device Name: NeedleCam HD™ Visualization System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, GCJ
Dated: January 29, 2015
Received: January 30, 2015

Dear Mr. Sanso:

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For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
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Public Health Service

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Silver Spring, MD 20993-0002

February 20, 2015

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

Re: K143705
Trade/Device Name: NeedleCam HD™ Visualization System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, GCJ
Dated: January 29, 2015
Received: January 30, 2015

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. 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.

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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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143705

Device Name
NeedleCam HD™ Visualization System

Indications for Use *(Describe)*
NeedleCam HD™ Visualization System

Indications for Use: The NeedleCam HD™ Visualization 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.

This is the same intended use as for a previously cleared device - the BioVision Technologies SurgView™ Integrated Visualization System (K082293).

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.

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BIO VISION Technologies, LLC
Visualizing Better Care

221 Corporate Circle, Suite H
Golden, Colorado 80401 USA
Phone: 303-237-9608 • Fax: 303-237-0757
www.biovisiontech.com

Needle Cam HD™ Visualization System
Special 510(k) Submission

SPECIAL 510(k) SUMMARY

Submission Information

Date Prepared: December 22, 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: NeedleCam HD™ Visualization System

Common Name: Arthroscope/Endoscope

Classification Name: Arthroscope / Endoscope and Accessories

Regulation Number: 21 CFR §888.1100, HRX

21 CFR §876.1500, GCJ

Regulatory Class: II

Predicate Device

BioVision Technologies SurgView™ Integrated Visualization System (K082293)

Device Description

Name of the Device: NeedleCam HD™ Visualization System

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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NeedleCam HD™ Visualization System is comprised of an Image Capture Box, a Camera Handpiece (including an LED light source) that captures still images and full resolution video, and External Power Supply. The camera has a quick-release optical connector that adapts to a wide variety of Bio Vision Technologies' surgical endoscopes. The device is used with an endoscope to visualize and illuminate an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures.

The BioVision endoscopes and supplemental instruments that were approved with the predicate SurgView Visualization System have not been changed.

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.

NeedleCam HD System Components and Accessories

The NeedleCam HD Visualization System is intended to be used with BioVision endoscopes. The following is a listing of the current compatible scopes, along with the applicable 510(k) clearance numbers.

Part Number	Description	510(k) Number
BVTKIT72-0L065	OnPoint 0 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-0L165	BioVision NeedleView 0 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-0L1A0	BioVision NeedleView 0 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R165	BioVision NeedleView 10 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R1A0	BioVision NeedleView 10 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R265	InnerVue II 10 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R2A0	InnerVue II 10 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293

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BVTKIT75-3R165	BioVision NeedleView 30 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT75-3R1A0	BioVision NeedleView 30 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT82-34001	BioVision NeedleView CH 3.4mm Scope Kit (including scope, cannula, dilator, tuohy needles, scalpel and guidewire	K141326

Comparison to Predicate Device

The table below shows relevant similarities and differences between the NeedleCam HD™ Visualization System and its predicate device – SurgView™ Integrated Visualization System (K082293).

APPLICANT DEVICE: NeedleCam HD™ Visualization System

PREDICATE DEVICE: SurgView™ Visualization System (K082293)

NOTE: **Relevant similarities are identified in bold text.**
Relevant differences are identified in underlined text.

PREDICATE COMPARISON CHART

I. GENERAL CHARACTERISTICS			PREDICATE DEVICE
ITEM	**FEATURE**	**NeedleCam HD Visualization System**	**SurgView™ Visualization System K082293**
1	**Device Description**	NeedleCam HD Visualization System **is a video endoscope/arthroscope imaging system consisting of the following components:** 1. **An Image Capture Box that includes image processor and** external power supply) 2. **Camera handpiece** including a LED light source. 3. **A semi-rigid Fiberoptic Scope in a variety of diameters, lengths, and viewing angles. Supplemental instruments include a cannula, trocar, obturator, and cannula plug.** 4. Media Capture USB System 5. **Video Outputs for external monitor**	The SurgView™ Visualization System **is a video endoscope/arthroscope imaging system consisting of the following components:** 1. **A Light Source/Display/Image Capture device that includes** an internal monitor, **image processor,** Xenon light source and internal power supply**.** 2. **Camera handpiece**. 3. **A semi-rigid Fiberoptic Scope in a variety of diameters, lengths, and viewing angles. Supplemental instruments for the scope include a cannula, trocar, obturator, and cannula plug.** 4. Media Capture CF Card System 5. **Video output for external monitor.**

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2	Intended Use	Needle Cam HD™ **Visualization 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, shoulder, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and cervix**.	The SurgView™ **Visualization 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, shoulder, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and cervix**.
3	Materials Used	**Plastic enclosure, media capture board**, **plastic camera cable.** **Scopes & instruments - Stainless Steel for Scope Shaft; Fiber Optics for light transmission**	**Plastic enclosure,** metal plate, **media capture board**, **plastic camera cable**, and fiber optic cable**.** **Scopes & instruments - Stainless Steel for Scope Shaft; Fiber Optics for light transmission**
4	Labeling (Single Use/Reusable)	**Image capture box and camera handpiece: Reusable.** **Scopes & instruments: Sterile, Single Use**	**Image capture box and camera handpiece: Reusable.** **Scopes & instruments: Sterile, Single Use**
5	Image acquisition	**Image acquisition is achieved through an endoscope attached to a camera handpiece. The endoscope is in the sterile field while the handpiece remains non-sterile. A barrier is provided to preserve the sterile field.**	**Image acquisition is achieved through an endoscope attached to a camera handpiece. The endoscope is in the sterile field while the handpiece remains non-sterile. A barrier is provided to preserve the sterile field.**
6	Connectivity	**The endoscope, camera handpiece, cable, illumination source and image processor connections allow functional coupling of the components while providing safe and reliable connections, in particular those related to electrical safety for the user and patient. The endoscope attached to the camera handpiece using a quick release connection.** The LED light source is included in the camera handpiece. **The camera cable connects to the image capture device using a single electrical connector.**	**The endoscope, camera handpiece, cable, illumination source and image processor connections allow functional coupling of the components while providing safe and reliable connections, in particular those related to electrical safety for the user and patient. The endoscope attached to the camera handpiece using a quick release connection.** The fiberoptic bundle is integrated with the camera cable. **The camera cable connects to the** light source**/image capture device using a single hybrid (electrical/optical) connector.**
7	Image processing	**The image is digitally processed to allow further manipulation, capture, printing, and multiple displays.**	**The image is digitally processed to allow further manipulation, capture, printing, and multiple displays.**
8	Image display (s)	**External monitor connection**	Internal monitor display with **external monitor connection.**
9	Data Entry	**Session information entered via external keyboard**	**Session information entered via external keyboard**

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10	Data storage	Image and video storage to USB device	Image and video storage to Compact Flash™ cards.
11	Where used	**Hospital / Doctor's office**	**Hospital / Doctor's office**
II. CHARACTERISTICS OF THE LIGHT SOURCE			
ITEM	FEATURE	**NeedleCam HD™ Visualization System**	**SurgView™ Visualization System K082293**
1	Illumination	**Illumination is achieved via** an internal LED light source. **The** LED **light source is an integral part of the device.** The LED is internal to the camera handpiece. **LED and Xenon usable light output is equivalent.**	**Illumination is achieved via** a fiberoptic bundle attached to the endoscope**. The** Xenon **light source is an integral part of the device.** The Xenon light source is internal to the image capture box. **LED and Xenon usable light output is equivalent.**
2	Type of light source	LED	Xenon
3	Lamp power rating	1W	35W
4	Rated lamp life	20,000 hours	3,000 hours
5	Luminous intensity as measured at scope output	**4-6 lumens**	**4-6 lumens**
III. CHARACTERISTICS OF THE CAMERA			
ITEM	FEATURE	**NeedleCam HD™ Visualization System**	**SurgView™ Visualization System**
1	Camera sensor	**¼" CCD**	**¼" CCD**
2	Sensor resolution	**768(H) x 494(V) pixels**	**768(H) x 494(V) pixels**
3	Camera resolution	**480 lines, interlaced**	**480 lines, interlaced**
4	Camera sterility	**Non sterile. Drape is used for sterile field preservation.**	**Non sterile. Drape is used for sterile field preservation.**
5	Endoscope coupler	**Built-in**	**Built-in**

Conclusion: Based on the evaluation of the performance characteristics, construction, manufacturing processes, and indications of use, BioVision Technologies has concluded that the BioVision NeedleCam HD ™ Visualization System is substantially equivalent to the predicate device listed in this submission.

The upgrades were completed to incorporate the improved light source options provided by LED lighting. The industry standard for media storage has moved from CF cards to USB technology. Additionally, analog television technology has been replaced by digital television technology.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Summary of Technologies

The technological characteristics of the BioVision NeedleCam HD™ Visualization System are similar to its predicate device – BioVision SurgView™ Visualization System (K082293). The indications and contraindications listed in this submission are in congruence between these devices. The modifications are incremental changes to the predicate image capture box and camera handpiece that do not affect safety and effectiveness of the modified device. The modifications are the following:

1) Update the image capture box to the current standard USB storage device;
2) Update the existing video format to the current digital format.
3) The camera handpiece has been upgraded with an LED light source.

We believe these modifications are eligible for the Special 510 (k) process since they have the same fundamental scientific technology and intended use as the predicate device.

Performance Testing

Establishment of equivalence is based on similarities of intended use, design, physical characteristics and geometry between the BioVision NeedleCam HD™ Visualization System and its predicate device – BioVision SurgView™ Visualization System (K082293).

Safety testing was completed to ANSI/AAMI ES 60601-1:2005 (3rd edition) on the BioVision NeedleCam HD™ Visualization System. Additionally software validation was completed on the system.

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 Needle Cam HD and its predicate device.

Conclusion

Based on the evaluation of the performance characteristics, construction, manufacturing processes, and indications of use, BioVision Technologies has concluded that the BioVision Needle Cam HD™ Visualization System is substantially equivalent to the predicate device listed above. In all cases, the characteristics of this device are identical or similar to the predicate device as they relate to the intended uses or application. BioVision Technologies has also determined that the modification is an incremental change to the existing device that does not affect safety and effectiveness of the device.

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SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE RE: DOCUMENT NUMBER K143705/S1

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   This change was for:

(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information

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(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information

[redacted]

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	Yes	No	
(Identify the new device and the predicate device) 1. Is the predicate device legally marketed?	yes		If **YES** = Go To 2 If **NO** = Stop **NSE**
(Review all labeling and assure that it is consistent with IFU statements) 2. Do the devices have the same intended use?	yes		If **YES** = Go to 3, Respond to "A." below If **NO** = Stop **NSE**, Respond to "A." below
(Review design, materials, energy source and other features of the devices) 3. Do the devices have the same technological characteristics?	yes		If **YES** = Stop **SE** If **NO** = Go to 4, Respond to "B." below
(Determine what questions of safety and effectiveness the different technological characteristics raise) 4. Do the different technological characteristics of the devices raise different questions of safety and effectiveness?			If **YES** = Stop **NSE**, Respond to "C." below If **NO** = Go to 5
(Review the proposed scientific methods for evaluating new/ different characteristics' effects on safety and effectiveness) 5a. Are the methods acceptable?			If **YES** = Go to 5b If **NO** = Stop N**SE**, Respond to "D." below
(Evaluate performance data) 5b. Do the data demonstrate substantial equivalence?			If **YES** = Stop **SE,** Respond to "E." below If **NO** = Stop N**SE**, Respond to "E." below

Note: Please complete the following table and answer the corresponding questions.

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A. Please explain how the intended use of the subject device is similar to or different from the predicate device. Upgrades to a LED light source, video output to industry standard digital format, and use of commercial standard USB storage device.

B. Please describe the different technological characteristics. No substantial differences.

C. Please explain how the technological characteristics raise different questions of safety and effectiveness.

D. Please explain why the proposed scientific method for evaluating new/ different characteristics' effects on safety and effectiveness are not acceptable.

E. Please explain how the data do or do not demonstrate substantial equivalence.

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off (optional)	
Division Sign-Off (optional)	

Revised: 8/1/03
10/16/2012 – MMJ placed in Digital Signature format
1/28/13; GKP: Division digital signature optional
2/7/2013 – MMJ: BC signature optional. Per Barb's latest update (2/6/13), review memos and checklists only need to be digitally signed by the reviewer. No other signatures are required. The logging out of a document in CTS and, when applicable, the signing of the letter, is considered an appropriate and sufficient indicator that the review memo or checklist was reviewed by each level of management.
6/5/14: ERJ removed Sections 5c and 6 per Patrick Axtell
9/9/14:FXR replaced the SE decision table to be aligned with the new 510(k) guidance document
9/18/2014: FXR revised the SE decision table, question #4.

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Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K143705 Date Received by DCC: Dec 31, 2014

Lead Reviewer: Dwight Yen

Branch: GSDB2 Division: DSD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Special 510(k) Criteria

The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

	Yes	No
1) 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	X	
Comments?		
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	X	
Comments?		
3) Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	X	
Comments?		
4) The submission includes only summary-level information (i.e., NO test reports with performance data). *Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.*	X	
Comments?		

Does the submission meet all 4 criteria above?

- (●) Yes, submission meets criteria for a Special 510(k). Continue with the remainder of this checklist below.
- ( ) No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist; convert to a Traditional using the form below and apply the Traditional checklist.

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Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also 510(k) Summary Checklist)*	X			
b) Statement contains all elements per 21 CFR 807.93				
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.*	X			
6) Submission contains Class III Summary and Certification. *See recommended content.*			X	
7) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			
8) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.			X	
B. Device Description				
9)				
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
11) A description of all device modification(s) including rationale for each modification.	X			
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 10(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	X			
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			
D. Design Control Activities				
17) Design Control Activities Summary includes all of the following:				
a) Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis.	X			
b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.	X			
c) Declaration of conformity with design controls, including: *All 3 must be present to answer "Yes."* *i.* Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. *ii.* Statement that manufacturing facility is in conformance with design control procedure requirements as specified in *21 CFR 820.30*. *iii.* Statement is signed by the individual responsible for these activities.	X			
E. Proposed Labeling (see also 21 CFR part 801)				
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			
a) All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	X			
19) Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).	X			

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Decision: (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Dwight Yen 2015.01.08 10:34:46 -05'00'
Branch Chief Sign-Off (digital signature optional)*	Joshua C. Nipper -S 2015.01.08 11:17:48 -05'00'
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with with decision required. Branch and Division digital signature optional.