FEB 10 2012.

510(k) Summary

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

A. Name and Address of Applicant

Spine View, Inc.
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Fremont, CA 94538
Phone: (510) 743-5090
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B. Contact Person

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C. Date Prepared

November 11, 2011

D. Device Name

Trade Name:	SpineVu Endoscopic Spine System (SESS)
Common Name:	Arthroscope
Classification Name:	Arthroscope

E. Device Classification

Classification:	21 CFR §888.1100
Product Code:	HRX
Device Class:	Class II

F. Predicate Device

The modified SpineVu Endoscopic Spine System (SESS) is substantially equivalent to the Spine View SpineVu Endoscopic Spine System (SESS) (K081051), Spine View enSpire Discectomy System (K110992), Endius Atavi System (K061345), Richard Wolf Minimally Invasive Spinal Surgery Set (K994363), and Karl Storz Percutaneous Foraminoscopy Set (K001918).

G. Device Description

The SpineVu Endoscopic Spine System (SESS) is a collection of arthroscopic surgical accessories provided sterile (irradiated) and intended for single-use only. As a group,

the accessories are provided to facilitate delivery of an endoscope and other instruments to the targeted treatment site. The SpineVu Endoscopic Spine System (SESS) consists of the following devices.

- **enVue Cannula** - a device which provides access into the body for performing procedures in and around the spine. The enVue Cannula is provided with two different tip configurations (Standard Jaw and Long Jaw).
- **enVue Sheath** - a device that may be used to facilitate the delivery of a flexible endoscope (up to 2 mm diameter) through the working lumen of the enVue Cannula.
- **16G Introducer Cannula with Stylet** - facilitates initial access to the treatment site. The Introducer Cannula is used in conjunction with the **Introducer Stylet**.
- **Guidewire** - (16" long with a diameter of 0.058") may be used to facilitate exchange of the Introducer Cannula for the Dilator.
- **Dilator** - is designed to fit over the Guidewire and inside the Beveled Cannula. The Dilator is used to bluntly dissect soft tissue in order to provide a pathway for the Beveled Cannula.
- **Beveled Cannula** - is designed to fit over the Dilator. The Beveled Cannula comes in two lengths (5.4" and 6.1"). It provides an access path to the targeted treatment site for other instruments, such as the enVue Cannula.
- **Ball-Tipped Probe** - is used to probe or palpate tissue or bone.
- **Infusion Cannula** - is used to introduce fluids to the treatment site.
- **Suction Cannula** - is used to aspirate materials from the treatment site.

H. Intended Use

Surgical accessories are indicated for facilitating endoscopic access and visualization in the surgical area of the cervical, thoracic, or lumbar spine for interventional spinal procedures such as discectomy, nucleotomy and foraminotomy.

I. Technological Comparison

The SpineVu Endoscopic Spine System (SESS) has similar features as compared to the predicate devices as shown in the tables below:

Manufacturer	Zimmer (Endius)	Spine View, Inc.	Richard Wolf	Karl Storz	Spine View, Inc.	Spine View, Inc.
Device Name	Atavi System	enSpire Discectomy System	Minimally Invasive Spinal Surgery Set	Percutaneous Foraminoscopy Set	SpineVu Endoscopic Spine System	SpineVu Endoscopic Spine System
510(k) #	K061345	K110992	K994363	K001918	K081051	K113362
Indications for Use	Posterior or anterior access and visualization in the surgical area of the cervical, thoracic, or lumbar spine allowing the surgeon to perform any type of surgical spinal procedures such as discectomy, nucleotomy, spinal fusion, spinal decompression, and insertion of spinal implants. Other examples of generic surgical use of the Endius Atavi System would be for use in the knee, ankle, shoulder, hand, wrist, and temporomandibular joint (TMJ).	Cutting, grinding and aspirating intervertebral disc material during discectomy procedures in the cervical, thoracic and lumbar spine.	Examination, diagnosis, and/or therapy by personnel trained and qualified in connection with endoscopically used accessories in various medical disciplines, such as orthopedic and spinal surgery.	Visualize and treat verterbral disc herniations in the lumbar region of the spine using a posterolateral approach and fluoroscopic control.	Endoscopic access and visualization in the surgical area of the cervical, thoracic, or lumbar spine and are accessorized with surgical and coagulation tools for interventional spinal procedures such as discectomy, nucleotomy and foraminotomy.	Surgical accessories are indicated for facilitating endoscopic access and visualization in the surgical area of the cervical, thoracic, or lumbar spine for interventional spinal procedures such as discectomy, nucleotomy and foraminotomy.
Product Code	HRX	Same	Same	Same	Same	Same
Classification Section	Class II	Same	Same	Same	Same	Same

Manufacturer	Zimmer (Endius)	Spine View, Inc.	Richard Wolf	Karl Storz	Spine View, Inc.	Spine View, Inc.
Device Name	Atavi System	enSpire Discectomy System	Minimally Invasive Spinal Surgery Set	Percutaneous Foraminoscopy Set	SpineVu Endoscopic Spine System	SpineVu Endoscopic Spine System
510(k) #	K061345	K110992	K994363	K001918	K081051	K113362
Target Anatomy	Intervertebral procedures	Same	Same	Same	Same	Same
Target Population	Minimally invasive access, for various procedures in patients indicated for spinal surgery	Same	Same	Same	Same	Same
Instruments	1. Endoscope 2. Light source 3. Light guide 4. Camera control unit 5. Camera head 6. Retracting device 7. Access instruments	1. Discectomy device 2. 16G Introducer Cannula with Stylet	1. Punches 2. Rongeurs 3. Osteotomes 4. Elevators 5. Spoons 6. Curettes 7. Probes 8. Bone Pusher 9. Block applicator 10. Compaction tube 11. Swivel arm	1. Foraminoscope 2. Various accessories	1. 15G Needle 2. SpineVu Guide Wire 3. SpineVu Dilator 4. SpineVu Introducer Sheath 5. SpineVu Infusion Cannula 6. SpineVueBalloon Cannula 7. SpineVue Debrider 8. SpineVu CoagProbe 9. SpineVu Grasper 10. SpineVu MiniScope	1. 16G Introducer Cannula w/ Stylet 2. Guidewire 3. Dilator 4. Beveled Cannula 5. enVue Cannula (Standard Jaw or Long Jaw) 6. enVue Sheath 7. Ball Tipped Probe 8. Suction Cannula 9. Infusion Cannula

Manufacturer	Zimmer (Endius)	Spine View, Inc.	Richard Wolf	Karl Storz	Spine View, Inc.	Spine View, Inc.
Device Name	Atavi System	enSpire Discectomy System	Minimally Invasive Spinal Surgery Set	Percutaneous Foraminoscopy Set	SpineVu Endoscopic Spine System	SpineVu Endoscopic Spine System
510(k) #	K061345	K110992	K994363	K001918	K081051	K113362
Design	Dilatation Access Retraction Visualization	Dilatation Access Excision	Dissection Manipulation Excision	Dilatation Access Visualization	Dilatation Access Retraction Excision Aspiration/Infusion Visualization	Dilatation Access Retraction Aspiration/Infusion
Endoscope Compatibility	OD up to approximately 0.944"	OD up to 0.058"	OD up to 0.271"	OD up to 0.236"	OD up to 0.032"	OD up to 0.079"
Supplied Sterile/Sterilization Method	No	Yes/Gamma radiation	No	No	Yes/E-beam	Yes/E-beam
Single Use Only	No	Yes	No	No	Yes	Yes

enVue Cannula and enVue Sheath

	Predicate	Predicate	Subject	
Company, K#	**Endius, K061345**	**Spine View, SpineVu Endoscopic Spine System, K081051**	**Spine View, SpineVu Endoscopic Spine System K113362**	
Device Name	**Atavi System**	**SpineVu Balloon Cannula**	**enVue Cannula**	**enVue Sheath**
Indications for Use	Posterior or anterior access and visualization in the surgical area of the cervical, thoracic, or lumbar spine allowing the surgeon to perform any type of surgical spinal procedures such as discectomy, nucleotomy, spinal fusion, spinal decompression, and insertion of spinal implants. Other examples of generic surgical use of the Endius Atavi System would be for use in the knee, ankle, shoulder, hand, wrist, and temporomandibular joint (TMJ).	Cutting, grinding and aspirating intervertebral disc material during discectomy procedures in the cervical, thoracic and lumbar spine.	Facilitating endoscopic access and visualization in the surgical area of the cervical, thoracic, or lumbar spine for interventional spinal procedures such as discectomy, nucleotomy and foraminotomy. Same	
Intended Use	1. Access portal with working channel for instruments - facilitating endoscopic access and visualization in the surgical area of the spine for use during interventional spinal procedures 2. Distal feature for retracting tissue away from end of cannula -articulating portal with retracting jaws that mechanically actuate to retract tissue away from end of cannula	1. Access cannula with working channels for endoscope, endoscopic instruments, and irrigation and drainage 2. Distal feature for retracting tissue away from end of cannula	1. Access cannula with working channel for endoscope, endoscopic instruments, and irrigation and drainage 2. Distal feature for retracting tissue away from end of cannula	1. Intended for use with the enVue Cannula to provide the access ports for endoscopic instruments and endoscope, and irrigation

	Predicate	Predicate	Subject	
Company, K#	**Endius, K061345**	**Spine View, SpineVu Endoscopic Spine System, K081051**	**Spine View, SpineVu Endoscopic Spine System K113362**	
Device Name	**Atavi System**	**SpineVu Balloon Cannula**	**enVue Cannula**	**enVue Sheath**
Product Code	HRX	HRX	Same	Same
Design	Articulating portal with retracting jaws mechanically actuated to retract tissue away from end of cannula Articulating single lumen portal with retracting jaws used to dilate and maintain access which can accommodate the following: a) Flexible Endoscope b) Endoscopic Instruments c) Irrigation/Drainage	Toroidal balloon can be inflated to mechanically retract tissue away from the end of the cannula Single, multi-lumen device which can accommodate the following: a) Flexible Endoscope b) Endoscopic Instruments c) Irrigation/Drainage	Articulating Top Jaw can be mechanically actuated to retract tissue away from end of cannula Distal tip: Articulating jaw (Nylon) for tissue retraction (Standard and Long jaw configurations)	When combined with the enVue Cannula, can accommodate the following a) Flexible Endoscope b) Endoscopic Instruments c) Irrigation/Drainage
Dimensions	1. OD: Unknown 2. Working Length: Unknown 3. Working channel for endoscopic instruments and endoscope: 0.945" x 1.18" 4. Length, Tissue Retraction Feature: 1.181 " 5. OD, Tissue Retraction Feature: 2.362"	1. OD: 0.140" 2. Working Length: ~7.5" 3. Length, Tissue Retraction Feature: up to 0.315" 4. OD, Tissue Retraction Feature: 0.248 " 5. Multiple Working channels for endoscopic instruments: ~0.049" 6. Working channel for endoscope: ~0.039"	1. OD: 0.282" 2. Working Length: 7.5" 3. Length, Tissue Retraction Feature 0.394" 4. OD, Tissue Retraction Feature: 0.354 " 5. Single Working Channel for enVue Sheath (for endoscopic instruments and endoscope): 0.240"	1. OD: 0.236" - Designed to be delivered through enVue Cannula 2. Working Length: 8.8" 3. Working Channel for endoscopic instruments: 0.122" 4. Working channel for endoscope: 2 mm
Materials	Unknown	Stainless Steel, PEBAX, Polyurethane, PVC, Polycarbonate	Nylon-12, Stainless Steel, Solder (Sn/Ag), Polycarbonate, Medical Grade Adhesive (Loctite 4018, Loctite 4013, Loctite 3311)	Stainless Steel, Solder (Sn/Ag), Polycarbonate, Tygon, Medical Grade Adhesive (Loctite 4018, Loctite 4013, Loctite 3311)

	Predicate	Predicate	Subject	
Company, K#	**Endius, K061345**	**Spine View, SpineVu Endoscopic Spine System, K081051**	**Spine View, SpineVu Endoscopic Spine System K113362**	
Device Name	**Atavi System**	**SpineVu Balloon Cannula**	**enVue Cannula**	**enVue Sheath**
Target Anatomy	Intervertebral procedures	Same	Same	Same
Supplied Sterile?	Yes	Same	Same	Same
Single Use?	Yes	Same	Same	Same

16G Introducer Cannula and Stylet

	Predicate	Subject
Company, K#	**Spine View, enSpire Discectomy System, K110992**	**Spine View, SpineVu Endoscopic Spine System**
Device Name	**Introducer Cannula with Stylet**	**16G Introducer Cannula and Stylet**
Indications for Use	Cutting, grinding and aspirating intervertebral disc material during discectomy procedures in the cervical, thoracic and lumbar spine.	Facilitating endoscopic access and visualization in the surgical area of the cervical, thoracic, or lumbar spine for interventional spinal procedures such as discectomy, nucleotomy and foraminotomy.
Intended Use	Penetrate skin and provide a conduit to targeted treatment site.	Same
Product Code	HRX	Same

Guidewire

Predicate	Subject
SpineVu Endoscopic Spine System, K081051	**Spine View, SpineVu Endoscopic Spine System**
SpineVu Guide Wire	**Guidewire**
Cutting, grinding and aspirating intervertebral disc material during discectomy procedures in the cervical, thoracic and lumbar spine.	Facilitating endoscopic access and visualization in the surgical area of the cervical, thoracic, or lumbar spine for interventional spinal procedures such as discectomy, nucleotomy and foraminotomy.
Maintaining access to the target site for exchange of the other accessories	Same
HRX	Same

	Predicate	Subject
Company, K#	**Spine View, enSpire Discectomy System, K110992**	**Spine View, SpineVu Endoscopic Spine System**
Device Name	**Introducer Cannula with Stylet**	**16G Introducer Cannula and Stylet**
Design	16G Introducer: Hollow Stainless Steel tube with a proximal luer Stylet: Solid Stainless Steel instrument with a tri-beveled tip	Same
Dimensions	Cannula Length: 7" Stylet Length 7.7" OD: 16G (0.068") ID: 0.060"	Same
Materials	Stainless Steel, Polycarbonate, Medical Grade Adhesive (Loctite 3311)	Same
Target Anatomy	Intervertebral procedures	Same
Supplied Sterile?	Yes	Same
Single Use?	Yes	Same

Predicate	Subject
SpineVu Endoscopic Spine System, K081051	**Spine View, SpineVu Endoscopic Spine System**
SpineVu Guide Wire	**Guidewire**
Sold Stainless Steel wire with sharp tip	Solid Stainless Steel wire with blunt tip
Length: 16.5" Diameter: 0.046"	Length: 16" Diameter: 0.058"
Stainless Steel	Same
Intervertebral procedures	Same
Yes	Same
Yes	Same

Dilator

	Predicate	Subject
Company, K#	SpineVu Endoscopic Spine System, K081051	Spine View, SpineVu Endoscopic Spine System
Device Name	SpineVu Dilator	Dilator
Indications for Use	Cutting, grinding and aspirating intervertebral disc material during discectomy procedures in the cervical, thoracic and lumbar spine.	Facilitating endoscopic access and visualization in the surgical area of the cervical, thoracic, or lumbar spine for interventional spinal procedures such as discectomy, nucleotomy and foraminotomy.
Intended Use	Provide a larger pathway through tissue for other instruments	Same
Product Code	HRX	Same
Design	Stainless Steel tube with tapered tip	Same
Dimensions	Length: 9" ID: 0.050" OD: 0.142"	Length: 9" ID: 0.063" (at tip) OD: 0.285"
Materials	Stainless Steel	Same
Target Anatomy	Intervertebral procedures	Same
Supplied Sterile?	Yes	Same
Single Use?	Yes	Same

Beveled Cannula

Predicate	Subject
SpineVu Endoscopic Spine System, K081051	Spine View, SpineVu Endoscopic Spine System
SpineVu Introducer Sheath	Beveled Cannula
Cutting, grinding and aspirating intervertebral disc material during discectomy procedures in the cervical, thoracic and lumbar spine.	Facilitating endoscopic access and visualization in the surgical area of the cervical, thoracic, or lumbar spine for interventional spinal procedures such as discectomy, nucleotomy and foraminotomy.
Provides a conduit for other instruments to treatment site.	Same
HRX	Same
Stainless Steel tube with straight tip	Stainless Steel tube with beveled tip
Length: 7" ID: 0.144" OD: 0.150"	Length, Short: 5.4" Length, Long: 6.1" ID: 0.291" OD: 0.312"
Stainless Steel, ABS, Polycarbonate	Stainless Steel
Intervertebral procedures	Same
Yes	Same
Yes	Same

Ball Tip Probe

	Predicate	Subject
Company, K#	Richard Wolf, Minimally Invasive Spinal Surgery Set, K994363	Spine View, SpineVu Endoscopic Spine System
Device Name	Probe	Ball Tip Probe
Indications for Use	Examination, diagnosis, and/or therapy by personnel trained and qualified in connection with endoscopically used accessories in various medical disciplines, such as orthopedic and spinal surgery.	Facilitating endoscopic access and visualization in the surgical area of the cervical, thoracic, or lumbar spine for interventional spinal procedures such as discectomy, nucleotomy and foraminotomy.
Intended Use	Bluntly probe tissue or bone	Same
Product Code	HRX	Same
Design	Retractable solid ball-tip wire with flexible blunted tip	Solid ball-tip wire shaft with ball with blunt tip
Dimensions	Length: 13.8" Diameter: 0.098"	Length: 12.4" Diameter, Shaft: 0.047" Diameter, Tip: 0.094"
Materials	Unknown	Stainless Steel, Brazing Paste (Ag/Cu/ Zn/Sn)
Target Anatomy	Intervertebral procedures	Same
Supplied Sterile?	No	Same
Single Use?	No	Same

Suction Cannula

Predicate	Subject
Karl Storz Percutaneous Foraminoscopy Set, K001918	Spine View, SpineVu Endoscopic Spine System
Suction Cannula	Suction Cannula
Visualize and treat verterbral disc herniations in the lumbar region of the spine using a posterolateral approach and fluoroscopic control.	Facilitating endoscopic access and visualization in the surgical area of the cervical, thoracic, or lumbar spine for interventional spinal procedures such as discectomy, nucleotomy and foraminotomy.
Aspirate fluid from the targeted treatment site	Aspirate fluid from the targeted treatment site
HRX	Same
Metal hypotube with proximal female luer hub and beveled distal tip	Metal hypotube with proximal barb fitting Blunt distal tip Designed to fit through working lumen of enVue Cannula/enVue Sheath
Length: 11.8" ID: 0.027" OD: 0.157"	Length: 12.2" ID: 0.106" OD: 0.120"
Stainless Steel	Stainless Steel, Acrylic, Medical Grade Adhesive (Loctite 3311)
Intervertebral procedures	Same
No	Same
No	Same

Infusion Cannula

	Predicate	Subject
Company, K#	**Spine View, SpineVu Endoscopic Spine System, K081051**	**Spine View, SpineVu Endoscopic Spine System**
Device Name	**SpineVu Infusion Cannula**	**Infusion Cannula**
Indications for Use	Cutting, grinding and aspirating intervertebral disc material during discectomy procedures in the cervical, thoracic and lumbar spine.	Facilitating endoscopic access and visualization in the surgical area of the cervical, thoracic, or lumbar spine for interventional spinal procedures such as discectomy, nucleotomy and foraminotomy.
Intended Use	Infusion of solutions into the disc material and spinal cavity	Same
Product Code	HRX	Same
Design	Metal hypotube with beveled tip; proximal female luer fitting	Metal hypotube with beveled tip; proximal female barb fitting
Dimensions	Length: 13" ID: 0.027" OD: 0.042"	Length: 13.4" ID: 0.027" OD: 0.042"
Materials	Stainless Steel	Stainless Steel, Polycarbonate, Medical Grade Adhesive (Loctite 3311)
Target Anatomy	Intervertebral procedures	Same
Supplied Sterile?	Yes	Same
Single Use?	Yes	Same

The technological characteristics and principals of operation of the modified SpineVu Endoscopic Spine System (SESS) are substantially equivalent to the named predicate devices.

J. Non-Clinical Performance Data

The following non-clinical testing was conducted to support a determination of substantial equivalence to the predicate device.

• Visual and Dimensional Verification	• Jaw Cycle Integrity Testing
• Device to Device Compatibility Testing	• Jaw Activation Testing
• Tensile Testing	• Biocompatibility Testing
• Flow Rate Testing	• Design Validation Testing
• Luer Attachment Testing	• Packaging Testing
• Leakage Testing	• Sterility Testing
• Jaw & Trigger Force Testing	

The above testing confirmed that the SpineVu Endoscopic Spine System (SESS) performs according to the stated intended use. All data fell well within product specifications and external standard requirements. Results of non-clinical testing demonstrated that the SpineVu Endoscopic Spine System (SESS) is substantially equivalent to the predicate devices for its intended use.

K. Conclusions

The SpineVu Endoscopic Spine System (SESS) has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, non-clinical testing was conducted to validate the performance of the device and ensure the modified SpineVu Endoscopic Spine System (SESS) functions as intended and meets design specifications. The comparison and non-clinical results demonstrate that the device is substantially equivalent to the predicate device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

FEB 10 2012

Spine View, Inc.
% Ms. Sevrina Ciucci
48810 Kato Road, Suite 100E
Fremont, California 94538

Re: K113362
Trade/Device Name: SpineVu Endoscopic Spine System (SESS)
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: January 11, 2012
Received: January 13, 2012

Dear Ms. Ciucci:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Dep Dir

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K_____

Device Name: SpineVu Endoscopic Spine System (SESS)

Indications for Use:

Surgical accessories are indicated for facilitating endoscopic access and visualization in the surgical area of the cervical, thoracic, or lumbar spine for interventional spinal procedures such as discectomy, nucleotomy and foraminotomy.

Prescription Use ___X___ **Or** **Over-The-Counter Use** _____

(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark P. Dyke for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113362