Section 5: 510(k) Summary

AUG - 7 2008

Device Information:

Category	Comments
Sponsor:	Roy Chin President & CEO SpineView, Inc 48541 Warm Springs Blvd. Suite 507 Fremont, CA 94539 Tel: 510-377-0898
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140 Fax: 510-337-0416
Device Common Name:	Arthroscopic Intervention Kit
Device Classification & Code:	Arthroscope: Class II, HRX Arthroscope Accessories: Class I, NBH Electrosurgical Accessory: Class II, GEI
Device Classification Name:	21CFR888.1100: Arthroscope & Accessories 21CFR878.4400: Electrosurgical Cutting & Coagulation Device and Accessories
Device Proprietary Name:	SpineVu Endoscopic Spine System (SESS) SpineVu MiniScope

Predicate Device Information:

Predicate Devices:	Kess Instrument set	Disc-FX System	Perc-D Spine Wand
Predicate Device Manufacturers:	Richard Wolf Medical Instruments	Ellman International	ArthroCare
K#s	K000046	K052241	K010811
Predicate Device Common Name:	Arthroscope & accessories	Arthroscope & accessories; electrosurgical accessories	Arthroscope & accessories; electrosurgical accessories
Predicate Device Classification:	21CFR888.1100: Arthroscope & Accessories	21CFR888.1100: Arthroscope & Accessories 21CFR878.4400: Electrosurgical Cutting & Coagulation Device and Accessories	21CFR888.1100: Arthroscope & Accessories 21CFR878.4400: Electrosurgical Cutting & Coagulation Device and Accessories

Predicate Device Classification & Code:	Class 2, HRX	Class 2, HRX & GEI	Class 2, HRX & GEI

Predicate Device Information, continued:

Predicate Devices:	Kinetics Interchangeable Spine System	Atavi System
Predicate Device Manufacturers:	**Arthro Kinetics**	**Endius**
K#s	K061246	K061345
Predicate Device Common Name:	Arthroscope & accessories	Arthroscope & accessories
Predicate Device Classification:	21CFR888.1100: Arthroscope & Accessories	21CFR888.1100: Arthroscope & Accessories
Predicate Device Classification & Code:	Class 2, HRX	Class 2, HRX

b. Date Summary Prepared
10 April 2008

c. Description of Device
The SESS kit is a collection of arthroscopic surgical accessories, including a bipolar RF electrosurgical accessory. The SpineVu MiniScope is an arthroscope.

d. Intended Use
The SpineVu Endoscopic Spine System (SESS™) and SpineVu MiniScope are indicated for use for 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.

e. Comparison to Predicate Device
SESS Kit
Nearly all of the components of the SESS kit are Class I exempt (NBH) as Arthroscope accessories (21CFR888.1100). The only exception is the SpineVu CoagProbe. The CoagProbe is a Class II electrosurgical accessory (21CFR878.4440, GEI).

The SpineVu CoagProbe is substantially equivalent in intended use as the coagulation probes found in the Arthrocare Perc-D Spine Wand (K010811) and the Ellman Disc-FX Systems (K052241). Each is used for the ablation and coagulation of intervertebral disc material. The designs of the probes are similar in that all are intended to be used under direct visualization via an endoscope. All of the probes are bipolar and use RF energy to ablate and coagulate the disc material.

SpineView concludes that the SESS is substantially equivalent to the predicate arthroscopic surgical kits.

SpineVu MiniScope

The SpineVu MiniScope is substantially equivalent in intended use and design as the arthroscopes in the "Kess" instrument set (K000046), the Arthro Kinetics Spine System (K061246) and the Endius Atavi System (K061345). All are fiber-optic illumination and visualization systems for percutaneous evaluation of intervertebral spaces in the spinal column.

SpineView concludes that the SpineVu MiniScope is substantially equivalent to the predicate arthroscopes.
The testing described below demonstrates that the differences in the devices do not raise any unresolved issues of safety or efficacy.

SpineView concludes that the devices are substantially equivalent.

f. Summary of Supporting Data

Biocompatibility data demonstrates that the device is in compliance with ISO 10993.

Bench testing has demonstrated that the device is in compliance with pertinent standards, the medical communities expectations, and the product labeling.

Cadaver testing demonstrated that the device can be used as intended in humans

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2008

Spine View, Inc.
% Coombs Medical Device Consulting, Inc.
Mr. Craig Coombs
1193 Sherman Street
Alameda, California 94501

Re: K081051
Trade/Device Name: SpineVu Endoscopic Spine System (SESS™) and SpineVu MiniScope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX, GEI
Dated: July 18, 2008
Received: July 22, 2008

Dear Mr. Coombs:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known):

Device Name: SpineVu Endoscopic Spine System (SESS™) and SpineVu MiniScope

Indications For Use:

The SpineVu Endoscopic Spine System (SESS™) and SpineVu MiniScope are indicated for use for 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.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081051