Section 5: 510(k) Summary

Device Information:

Category	Comments
Sponsor:	SpineView, Inc. 48541 Warm Springs Blvd., Suite 507 Fremont, CA 94539
Correspondent Contact Information:	Sandra Sundell Director, Regulatory Affairs SpineView, Inc. 48541 Warm Springs Blvd., Suite 507 Fremont, CA 94539 Tel: 510 585-5345 Fax: 510 623-1093 Email:ssundell@spineview.com
Device Common Name:	Arthroscope and Accessories
Device Classification & Code:	Arthroscope: Class II, HRX Arthroscope Accessories: Class I, NBH
Device Classification Name:	21 CFR § 888.1100 Arthroscope and Accessories
Device Proprietary Name:	ENSPIRE™ Debrider System

Predicate Device Information:

Predicate Devices:	Stryker Dekompressor Percutaneous Discectomy Probe	SpineVu Endoscopic Spine System (SESS)
Predicate Device Manufacturers:	Stryker Instruments	SpineView, Inc.
K#s	K032473	K081051
Predicate Device Common Name:	Percutaneous Discectomy Probe Arthroscopic Intervention Kit	Arthroscopic Intervention Kit
Predicate Device Classification:	21CFR888.1100: Arthroscope & Accessories	21CFR888.1100: Arthroscope & Accessories
Predicate Device Classification & Code:	Class II, HRX	Class II, HRX

b. Date Summary Prepared

February 3, 2009

c. Description of Device

The SpineView ENSPIRE™ Debrider is a single-use discectomy device that is designed to cut and grind intervertebral disc material. Its auger mechanism retrieves the excised debris and ejects it into a collection chamber.

d. Intended Use

The SpineView ENSPIRE™ Debrider is intended for use in cutting, grinding and aspirating intervertebral disc material during discectomy procedures in the cervical, thoracic and lumbar spine.

e. Comparison to Predicate Device

The SpineView ENSPIRE™ Debrider is substantially equivalent in intended use and technology to the currently marketed predicate devices the Debrider component of the SpineVu Endoscopic Spine System (K081051) and the Stryker Dekompressor Percutaneous Discectomy Probe (K032473). Both the Application device and the predicate devices provide a means to aspirate and grind disc material during discectomies in the lumbar, thoracic and cervical regions of the spine. The SpineView ENSPIRE™ Debrider and the predicate devices are all intended to be used to cut and remove diseased disc material in the same anatomical location.

f. Summary of Supporting Data

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

Bench testing has demonstrated that the device is in compliance with the pertinent standards, the expectations of the medical community 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

Spine View, Inc.
% Ms. Sandra Sundell
Director, Regulatory Affairs
48541 Warm Springs Boulevard
Suite 507
Fremont, California 94539

APR 15 2009

Re: K090278
Trade/Device Name: ENSPIRE™ Debrider System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Product Code: HRX
Dated: March 23, 2009
Received: March 24, 2009

Dear Ms. Sundell:

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

for

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: ENSPIRE™ Debrider System

Indications For Use: The SpineView ENSPIRE™ Debrider is intended for use in cutting, grinding and aspirating intervertebral disc material during discectomy procedures in the cervical, thoracic and lumbar spine.

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)

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Neil R.P. Ogden for mkm

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

510(k) Number K090278