K091439
P. 1 of 3

Summary

This summary of a Traditional 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the SurgiVision Head Fixation Arc and Table Base.

1. **Company making the submission:**

AUG 2 5 2009

Name of Owner:	**SurgiVision, Inc.**
Address:	**5 Musick** **Irvine, CA 92618**
Telephone:	**949-900-6833**
Fax:	**949-900-6834**
Contact:	**Edward Waddell**
E-mail:	**Ewaddell@surgivision.com**
Correspondent:	J. Harvey Knauss
Address:	11984 South Evelyn Circle Houston, Texas 77071-3404
Telephone:	713-723-4080
Fax:	713-723-0786
E-mail:	harvey.knauss@gmail.com

2. **Device Name:**

Common Name:	Neurological head holder
Proprietary Name:	Head Fixation Arc and Table Base
Regulation Number:	882.4460
Product Code:	HBL

3. **Predicate Device:**

K071179, Noras OR Head Holder, Siemens Medical Solutions USA, Inc. Malvern PA 19355 and K874298, Malcolm-Rand Micro neurosurgical Cranio-XRay Frame. Engineered Orthopedic Technologies, Inc., San Clemente, CA.

K091439
p. 2 of 3

4. **Intended Use Statement:**

   The Head Fixation Arc and Table Base is intended for use as a device to clamp and hold the patients head in a particular position for procedures requiring Magnetic Resonance Imaging (MRI) of the brain structure and targets.

5. **Description of Device:**

   The Head Fixation Arc and Table Base is designed to immobilize the patients head during the surgical procedure. It has secondary design intent to provide mounting method for the headcoil and optional camera system. The patient's head is positioned inside the headcoil and attached rigidly to the Head Fixation Arc. The patients head never touches the head coil.

6. **Summary of the technological characteristics of the device compared to the predicate device:**

   The candidate device, this submission, has the same method of construction and use as the predicates.

7. **Testing:**

   Testing to applicable Standards has been completed with positive outcomes.

   Top level of testing performed:

   Performance Testing – Bench

8. **Rx or OTC:**

   The Head Fixation Arc and Table Base is an Rx prescription device per 21 CFR Subpart D.

K091439
P.3 of 3

9. **Conclusions:**

The Head Fixation Arc and Table Base is equivalent to the predicate devices in the scope of practical application, effectiveness at this application, and ensuring the safety of its subject.

The Head Fixation Arc and Table Base do not raise any new safety or effectiveness issues.

SurgiVision, Inc.

Edward Waddell

Edward Waddell
Director of Regulatory Affairs

Date: July 22, 2009

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

AUG 2 5 2009

SurgiVision, Inc.
c/o Mr. J. Harvey Knauss
Contract Consultant
Dephi Consulting Group (DCG)
11874 South Evelyn Circle
HOUSTON TX 77071

Re: K091439
Trade/Device Name: Head Fixation Arc and Table Base
Regulation Number: 21 CFR §882.4460
Regulation Name: Neurosurgical head holder (skull clamp)
Regulatory Class: II
Product Code: HBL
Dated: July 22, 2009
Received: July 28, 2009

Dear Mr. Knauss:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K091439

Device Name: Head Fixation Arc and Table Base

The Head Fixation Arc and Table Base is intended for use as a device to clamp and hold the patients head in a particular position for procedures requiring Magnetic Resonance Imaging (MRI) of the brain structure and targets.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The Counter Use (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 Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091439