510K K122662

5.0 SUMMARY

In accordance with Title 21 Code of Federal Regulations (21 CFR), Part 807, and in particular, §807.92, the following 510(k) summary is provided for the VertiFlex® Direct Decompression System:

5.1 Submitted By:

VertiFlex®, Incorporated
1351 Calle Avanzado
San Clemente, California 92673

NOV 1 3 2012

Contact: Steve Reitzler, Vice President, Clinical & Regulatory Affairs

Date Prepared: August 30, 2012

5.2 Device Name

Trade or Proprietary Name:	Direct Decompression System
Common or Usual Name:	Arthroscope Accessories
Classification Name:	Arthroscope

5.3 Predicate Devices

The subject device is substantially equivalent, in whole or in part, to the following commercially available predicate device:

Vertos Medical *mild*® Device Kit (Vertos Medical, Inc.; K093062)

We also note that the functions of some System components do not differ from those of a manual rongeur as described in §882.4840 (e.g., Baxano, Inc. iO-Flex® System; K062711), or from various orthopedic manual surgical instruments as described in §888.4540 (Class I; 510[K] exempt)

5.4 Device Description

The VertiFlex® Direct Decompression System consists of a group of instruments intended to assist in the performance of lumbar decompression through a minimally-invasive approach. The instruments include both reusable, and single-use disposable devices. In combination, these instruments include dilators and a cannula through which the user may gain access to the site of decompression, and several specialized instruments with which both bony and soft tissue may be removed to decompress the neural elements. The single-use disposable devices will be provided sterile, and the reusable devices will be provided non-sterile for sterilization by the user before use.

5.5 Intended Use

The subject device is indicated for use as follows:

The VertiFlex® Direct Decompression System is a set of specialized surgical instruments intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions.

5.6 Comparison to Predicate Devices

Comparisons of design characteristics and features have established that the subject VertiFlex® Direct Decompression System is substantially equivalent in design, materials, indications, and other features, to other predicate decompression kits or devices commercially available in the U.S.

5.7 Summary of Non-Clinical Tests

Non-clinical tests included the performance of simulated decompression surgery in human cadavers, conducted to validate the performance of the subject System.

5.8 Summary of Clinical Tests

No clinical testing was conducted to support this submission.

5.9 Conclusions

The results of testing and comparison demonstrated the substantial equivalence of the subject Direct Decompression System to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 13, 2012

VertiFlex®, Incorporated
% Mr. Steve Reitzler
Vice President. Clinical and
Regulatory Affairs
1351 Calle Avanzado
San Clemente, California 92673

Re: K122662
Trade/Device Name: VertiFlex® Direct Decompression System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: August 30, 2012
Received: August 31, 2012

Dear Mr. Reitzler:

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,

Peter D. Rumm -S

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

Enclosure

Indications for Use

510(k) Number (if known): K122662

Device Name: VertiFlex® Direct Decompression System

Indications for Use:

The VertiFlex® Direct Decompression System is a set of specialized surgical instruments intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices