12/26/98

XOMED®

K984363

510(k) Summary

1.0 Date Prepared
December 4, 1998

2.0 Submitter (Contact)
David Timlin
Xomed Surgical Products
Jacksonville, FL
(904) 279-7532

3.0 Device Name

Proprietary Name:	XPS Tissue Aspiration System XPS StraightShot or Model 2000 Microdebrider System (The proposed product tradename has not been finalized and may be changed at a later date)
Common Name(s):	Surgical Aspiration System
Classification Name:	Surgical instrument, AC powered motors and accessories / attachments Manual or powered portable aspiration pump

5.0 Device Classification
Surgical instrument, AC powered motors and accessories / attachments
Procode 79GEY Class I ; 21 CFR 878.4820 Exempt from 510k

Manual or powered portable aspiration pump
Procode 79BTA Class II ; 21 CFR 878.4780 Tier ?

6.0 Device Description
The XPS Tissue Aspiration System remains essentially the same as originally described in K963246. There is a Power Control Unit, a footswitch, reusable handpiece and various interchangeable, disposable cannulas. Suction is provided by either standard hospital wall vacuum or a commercially available medical aspirator.

7.0 Intended Use
The Xomed XPS Tissue Aspiration System is intended for the removal of tissue and fluids from the body during general surgical procedures.

8.0 Substantial Equivalence

The XPS System, with expanded indications that include tissue and fluid removal in general surgical procedures, is substantially equivalent to the following predicate devices that have been cleared for general removal of fluid and loose tissue:

Powered Aspiration System	
MicroAire "Powered Aspiration Device" PAD-100 (MicroAire Surgical Instruments)	K973268
Aspiration Cannulas	
Various aspiration cannulas (Wells Johnson Company)	K832520

The predicate systems described above have also been cleared for the removal of tissue and fluids in general surgical procedures. Generally, all of these systems involve a handpiece with a hollow, stainless steel cannula with one or more openings at the tip. The cannula come in various lengths and diameters with a variety of tip configurations . Connected to an active power unit or suction source, tissue (and fluid) is aspirated into the openings in the cannula tip while it is avulsed and suctioned off through the hollow shaft.

The XPS system is equivalent in that it also includes a handpiece with a cannula that is attached to a power unit. The only difference is that the cannula has an internal rotating cannula to morcelize the tissue into smaller pieces, making aspiration easier and to help prevent clogging. With continuous suction, the tissue is aspirated into the port or window in the outer cannula, morcelized by the rotary action of the inner cannula, and then easily suctioned upward through the shaft.

Like the XPS, the MicroAire "Powered Aspiration Device" PAD-100 (K973268) also uses powered cannulas to remove tissue and fluids. In contrast to the rotary action inside the XPS cannula, the entire PAD cannula rapidly reciprocates, simulating the back and forth manual motions of a surgeon. Although the reciprocating action is meant to facilitate the passage of the cannula through the tissue, the tissue is still rasped and torn to separate it for removal.

Laboratory testing demonstrates that the proposed XPS System will aspirate and penetrate tissue the same as the predicate suction cannulas. The use of a powered cannula is also not unique as demonstrated by the currently marketed MicroAire PAD. Although their dynamics are different, they are both intended to assist in the tissue removal process. The additional indication proposed for the XPS System, to remove tissue and fluid in general surgery, is equivalent to the current intended use of the XPS System, is the same as the predicate devices; and, the minor technological differences compared to the predicate devices raise no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 1999

Mr. David M. Timlin
Manager, Regulatory Affairs
XOMED, Inc.
6743 Southpoint Drive, North
Jacksonville, Florida 32216-0980

Re: K984363
Trade Name: XPS Tissue Aspiration System
Regulatory Class: II
Product Code: BTA
Dated: December 4, 1998
Received: December 7, 1998

Dear Mr. Timlin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 984363

Device Name: **XPS Tissue Aspiration System**

Indications for Use:

The Xomed XPS Tissue Aspiration System is intended for the removal of tissue and fluids from the body during general surgical procedures.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Or Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984363