

AUG 26 1997

ATTACHMENT 8

K972508

510(k) SUMMARY

Submitting Company: SYNVASIVE Technology, Inc.
4925 Robert J. Matthews Pkwy.
El Dorado Hills, CA 95762

Telephone: 916-939-3913

Fax: 916-939-3919

Contact Person: Michael G. Fisher
President and CEO

Date Prepared: June 13, 1997

Common Product Name: Surgical Burs and Surgical Drill Bits

Classification Name: Surgical Instrument Motors and
Accessories/Attachments (per 21 CFR
878.4820)

Product Description: The subject devices (surgical burs and surgical drill bits) are stainless steel and/or tungsten carbide devices which may be coated with abrasion resistant coatings in order to increase cutting efficiency. They will be supplied as both sterile and non-sterile devices and will be labeled for single use.

Intended Use: The surgical bur and surgical drill bit devices are for use during surgical procedures to cut hard tissue or bone and soft tissue.

Substantial Equivalence: The surgical bur and surgical drill bit devices are substantially equivalent to standard surgical burs and surgical drill bits legally marketed by many companies including DePuy, MicroAire, Synthes, and Zimmer.

Technological Characteristics: The surgical bur and surgical drill bit devices have the same technological characteristics as all of the predicate devices.

Safety and Effectiveness Testing: All materials used in the surgical bur and surgical drill bit devices conform with industry specifications for medical device use. Material specifications are tested on a design basis.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael Fisher
President and CEO
SYNVASIVE Technology, Inc.
4925 Robert J. Matthews Parkway
El Dorado Hills, California 95762

AUG 26 1997

Re: K972508
Trade Name: Surgical Burs and Surgical Drill Bits
Regulatory Class: I
Product Code: HWE
Dated: June 13, 1997
Received: July 3, 1997

Dear Mr. Fisher:

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 (Pre-market 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 requirements, 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

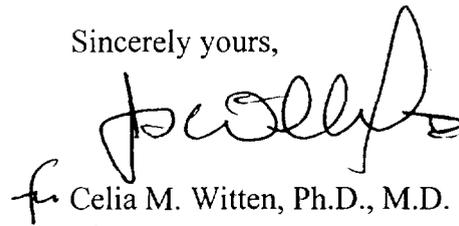
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devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

ATTACHMENT 9

INDICATION FOR USE STATEMENT

510 (k) Number: K972508

Device Name: Surgical Bur and Surgical Drill bit; per 21 CFR 878.4820, Surgical Instrument Motors and Accessories/Attachments

Indications for Use: Indications for use of the surgical bur and surgical drill bit devices are situations in surgical procedures where bone, hard tissue, or soft tissue is drilled, reamed, sculpted, augmented, reduced, replaced, or removed.

_____ Concurrence of CDRH, Office of Device Evaluations (ODE)

Prescription Use

OR Over-The-Counter Use

SYNVASIVE Technology, Inc

[Signature]
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972508

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