

JUN 29 1998

K9P1320

510(K) SUMMARY

DAUM BONE BIOPSY SET

Submitter Name: DAUM Corporation

Submitter Address: 1450 South Rolling Road
Baltimore, Maryland 21227

Contact Person: Pete Osborn

Phone Number: 410-455-5786

Facsimile Number: 410-455-5787

Date Prepared: 3 April 1998

Device Trade Name: DAUM Bone Biopsy Set

Device Common Name: Bone Biopsy Needle

Classification Name: Set, Biopsy Needle

Predicate Devices: DAUM Biopsy Needle

Device Description: The DAUM Bone Biopsy Set consists of a working tube, stylet, power drill drive, manual drill and an ejector drift. The drill is supplied as a disposable unit. All of the other components of the set are supplied as reusable products.

Intended Use: The DAUM Bone Biopsy Set is intended for the biopsy of bone tissue.

Device Technological Characteristics and Comparison to Predicate Devices(s): Both the DAUM Biopsy Needle and the Bone Biopsy Set are substantially equivalent in design, material, intended use and function.

Performance Data: The DAUM Bone Biopsy Set has been tested for MR Safety in a 0.2T static magnetic field and was found to be acceptable for patient use in this environment.

Conclusion: The DAUM Bone Biopsy Set which is intended for the biopsy of bone tissue is also a low-artifact-instrument designed to be used in the MRI for the above purpose.



JUN 29 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

• DAUM Corporation
c/ o Mr. Gary J. Sfeir, RAC
Greatbatch Scientific
9645 Wehrle Drive
Clarence, New York 14031

Re: K981320
Trade Name: DAUM Bone Biopsy Set
Regulatory Class: II
Product Code: KNW
Dated: April 7, 1998
Received: April 10, 1998

Dear Mr. Sfeir:

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.

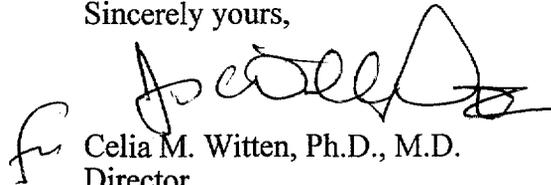
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Gary J. Sfeir

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,

A handwritten signature in black ink, appearing to read "C. Witten", is written over the typed name. The signature is fluid and cursive.

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):

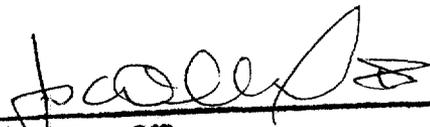
Device Name: DAUM Bone Biopsy Set

Classification Panel:

Indications for Use: *K 981320*

The DAUM Bone Biopsy Set is intended for the biopsy of bone tissue. The DAUM Bone Biopsy Set is also a low-artifact-instrument designed to be used in the MRI for the above purpose.

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number *K981320*

(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 _____