510(k) SUMMARY

K971036

SUBMITTED BY

Mario Gerzberg
President
ODONTIT S.A.
Av. Rivadavia 5032 1*7
1424 Buenos Aires
ARGENTINA
Telephone: 011-541-902-9500
Facsimile: 011-541-903-9330

JUN - 3 1997

Date Submitted: March 20, 1997

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Non-powered, Single Patitent, Portable Suction Apparatus
Common/Usual Name:	Disposable Aspirator
Proprietary Name:	Odontit Autogenous Bone Collection Device

PREDICATE DEVICE

KAM Super Sucker™ [reference 510(k) K822065 cleared 8/16/82]

DEVICE DESCRIPTION

The Odontit Autogenous Bone Collection Device is a portable suction device intended for use as an aspirator for the removal and collection of blood, autogenous bone, or other extraneous fluids from a surgical site. The device consists of the following components: Body Assembly, Aspirator Tip, Screen Filter, Flex tubing, Rigid tubing and a Plunger.

PRODUCT USE

1. The package is opened and the contents removed.
2. The rigid tubing connector is attached to a vacuum source.
3. The aspirator tip is attached to the flexible tubing.
4. The Autogenous Bone Collection Device is used in accordance with standard surgical procedures and as required to remove blood, autogenous bone chips or other extraneous fluids from the surgical site.
5. The lower body of the device is then aseptically separated from the upper body by twisting and carefully separating the two components.
6. The Screen Filter assembly is then carefully removed using aseptic technique.
7. Wash or rinse the collected bone chips per standard procedure if deemed necessary.

8. Use the plunger to compact the bone chips as required.
9. Remove the Filter Standoff to harvest the bone chips for delivery to the surgical site.

INDICATIONS FOR USE:

The Odontit Autogenous Bone Collection Device is indicated for use as an aspirator for the removal and collection of blood, autogenous bone chips, or other extraneous fluids from a surgical site. Using a vacuum source, the Odontititit aspirator will remove materials (including blood, bone chips and other fluids) from the surgical site and pass them through a stainless steel screen which is designed to capture and collect autogenous bone. At the option of the surgeon, this bone may be removed from the aspirator, washed and cleansed as necessary, and returned to the same patient as an autogenous bone graft.

The capacity for bone collection in the screen is approximately 16 cc.

WARNINGS AND PRECAUTIONS

Aseptic Technique Required

Warning: For one time use only - Do not resterilize.

Caution: Federal (USA) law restricts the use of this device to sale by or on the order of a licensed physician.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The product design, material of construction, and function as an aspirator is substantially equivalent to the FDA cleared predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 1997

Mr. Mario Gersberg
President
Interpore International
181 Technology Drive
Irvine, California 92618

Re: K971036
Trade Name: Odontit Autogenous Bone Collection Device
Regulatory Class: I
Product Code: GCY
Dated: March 20, 1997
Received: March 20, 1997

Dear Mr. Gersberg:

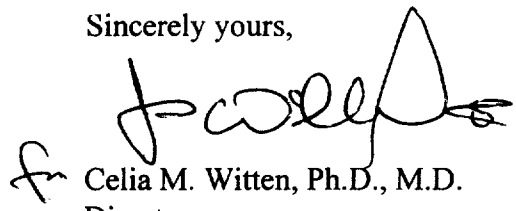
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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,



for 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): Not Known K971036

Device Name: Odontit Autogenous Bone Collection Device

Indications for Use:

The Odontit Autogenous Bone Collection Device is indicated for use as an aspirator for the removal and collection of blood, autogenous bone chips, or other extraneous fluids from a surgical site. Using a vacuum source, the Odontit aspirator will remove materials (including blood, bone chips and other fluids) from the surgical site and pass them through a stainless steel screen which is designed to capture and collect autogenous bone. At the option of the surgeon, this bone may be removed from the aspirator, washed and cleansed as necessary, and returned to the same patient as an autogenous bone graft.

The capacity for bone collection in the screen is approximately 16 cc.

(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 General Restorative Devices
510(k) Number K971036

Prescription Use ✓ OR Over-The-Counter Use
(PER 21 CFR 801.109)

(Optional Format 1-2-96)