OCT 30 1997

K972842

APPENDIX IV

510(k) SUMMARY

FOR

THE INTERPORE INDUCER BONE GRAFT DELIVERY SYRINGE

510(k) SUMMARY

SUBMITTED BY:

David P. Balding
Director, Quality Assurance and Regulatory Affairs
Interpore International
181 Technology Drive
Irvine, California 92618
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Date Submitted: July 31, 1997

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME:

Classification Name:	Piston Syringe
Common/Usual Name:	Bone Graft Delivery Syringe
Proprietary Name:	Interpore Inducer Bone Graft Delivery Syringe

PREDICATE DEVICES

Interpore 200 Coralline Hydroxyapatite Syringe Delivery System [reference 510(k) K841201 cleared 8/3/84] and the Grafton Allogeneic Bone Matrix Syringe dental LYC

DEVICE DESCRIPTION

The INTERPORE Inducer Bone Graft Delivery Syringe is a piston syringe intended for use to deliver allograft, autograft or synthetic bone graft materials to an orthopaedic surgical site. In addition, it is designed to facilitate pre-mixing of bone graft materials with I.V. fluids, blood, plasma, bone marrow or other specific blood component(s) as deemed necessary by the clinical use requirements. The Interpore Inducer has a volume of approximately 15cc.

The Interpore Inducer is a specially designed syringe specifically intended to deliver bone graft materials to a surgical site. It is supplied sterile in double aseptic transfer packaging.

The Interpore Inducer consists of a syringe barrel, syringe top cap, piston and plunger. The distal end of the syringe has a removable top cap which must be aseptically removed in order to load the bone graft material into the syringe. After loading the syringe, the top cap may be reattached to the syringe to constrain the contents of the syringe or to minimize potential

contamination of the syringe contents. In addition, the top cap has a male luer-lok connector which may be attached to any standard female luer adapter for fluid transfer.

The piston of the syringe is designed to eject fluids or blood components and bone graft materials into the operative site. It is also designed to be the attachment point for the syringe plunger. The proximal end of the piston also has a female luer-lok connector which may be connected to any standard male luer adapter for delivery of fluids or blood components into the syringe.

The syringe plunger is provided separately and is attached to the proximal end of the syringe piston immediately prior to bone graft expulsion from the syringe into the surgical site.

PRODUCT INTSTRUCTIONS FOR USE
ASEPTIC TECHNIQUE REQUIRED

1. Open outer package and, if desired, deliver sterile inner package onto a sterile field.
2. Open inner package.
3. Remove syringe barrel. Note that the syringe piston is already withdrawn. The volume of the syringe, when filled, is approximately 15cc.
4. Firmly grasp the syringe barrel with one hand and with the other hand rotate the top cap in a counter-clockwise direction.
5. Remove the top cap. Do not remove the luer cap.
6. Holding the syringe barrel upright, fill the syringe with the desired amount of bone graft material. If necessary, pack the material into the syringe removing as much air as practical.
7. Replace the top cap on the syringe barrel and rotate it in a clockwise direction to lock the cap in place.
8. If desired, add fluids to the graft material in the syringe by attaching a fluid delivery device to the female luer-lok located at the proximal end of the piston.
9. To flush fluids through the syringe, orient the syringe so that the top cap is below the piston. The vented male luer protector need not be removed for flushing.
10. To fill the syringe with fluid, hold the syringe with the top cap in the UP direction while filling the syringe through the syringe piston (i.e, fill from the bottom of the syringe). Disconnect fluid source when filling or flushing is complete.
11. Attach the syringe plunger handle to the female luer connector on the proximal end of the syringe piston. Firmly turn the plunger handle in a clockwise direction to tighten. **Caution:** Do not over-tighten.
12. For delivery of the graft material to a surgical site, remove the top cap and discard.
13. Gently expel syringe contents into the desired graft location. Discard the syringe after use.

WARNINGS

- This product is not intended for fluid injection into the circulatory system.
- Blood or blood products may require the use of an anti-coagulent prior to use.
- This product is for single use only. Do not resterilize.
- The Interpore Inducer is supplied sterile in individual double aseptic packages. The package should be inspected prior to use to ensure the sterility barrier has not been compromised.

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 a piston syringe is substantially equivalent to the FDA cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 30 1997

Mr. David P. Balding
Director, Quality Assurance and Regulatory Affairs
Interpore International
181 Technology Drive
Irvine, California 92618-2402

Re: K972842
Trade Name: Interpore Inducer Bone Graft Delivery Syringe
Regulatory Class: Unclassified
Product Code: LYC
Dated: July 31, 1997
Received: August 1, 1997

Dear Mr. Balding:

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) 594-4618. 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Not Known

Device Name: Interpore Inducer Bone Graft Delivery Syringe

Indications for Use:

The Interpore Inducer Bone Graft Delivery Syringe is indicated for the delivery of allograft, autograft or synthetic bone graft material to an orthopaedic surgical site. In addition, it is designed to facilitate pre-mixing of a bone graft material with I.V. fluids, blood, plasma, bone marrow or other specific blood component(s) as deemed necessary by the clinical use requirements.

The Interpore Inducer has a volume of approximately 15 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) Pamela D. Scott
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972542

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

(Optional Format 1-2-96)