

OCT 11 2002

K022415

510(K) SUMMARY

WaisMed LTD.

B.I.G™- Bone injection Gun for Pediatrics

Applicant: WaisMed Ltd.
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Caesarea, 38900
ISRAEL
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Contact Persons:

Dorit Winitz, Ph.D.
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
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Fax: 011- 972-9-7718131
E-mail: dorit@push-med.com

Trade Name:

B.I.G™- Bone Injection Gun for Pediatrics

Classification Name:

Needle, Hypodermic, Single Lumen

Predicate Devices

- The Bone Injection Gun Device (Waismed Ltd.), cleared under K981853
- The Intraosseous Access Needles (Cook Inc.), cleared under K915409, K913258

Intended Use:

The B.I.G™. Bone injection Gun for Pediatrics is intended to provide intraosseous access in the proximal tibia, as an alternative to IV access during emergencies. The device is for use in pediatric patients up to 12 years of age.

Device Description:

The B.I.G™. Bone injection Gun for Pediatrics is an instant, intravascular (IV) access device. The device comprises a housing with a spring loaded mechanism that inject a trocar needle into the bone marrow of a patient and allows for subsequent connection of a syringe or intravascular administration set.

Performance Data & Substantial Equivalence:

The B.I.G™. Bone injection Gun for Pediatrics, like both its predicates; the Adults' Model of the B.I.G.™ device and the Cook intraosseous Access Needles, is intended to provide intraosseous access as an alternative to intravascular access during emergencies. As the adult's model of the B.I.G.™ device it is limited for use in the proximal tibia and similarly to the Cook intraosseous Access Needles, the B.I.G.™ device is intended for use in the pediatric population.

The B.I.G™. Bone injection Gun for Pediatrics has the same technological features and principles of operation as the predicate Adults' B.I.G.™ device. Any minor differences in these aspects between the systems do not raise new types of safety or effectiveness issues as demonstrated by a supportive data including in vitro studies, clinical data and literature survey.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

WaisMed Limited
C/O Dr. Dorit Winitz
Push-med Limited
117 Ahuzah Street
Ra' anana 43373
ISRAEL

Re: K022415

Trade/Device Name: Bone Injection (B.I.G.) for Pediatrics
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: July 21, 2002
Received: July 24, 2002

Dear Dr. Winitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

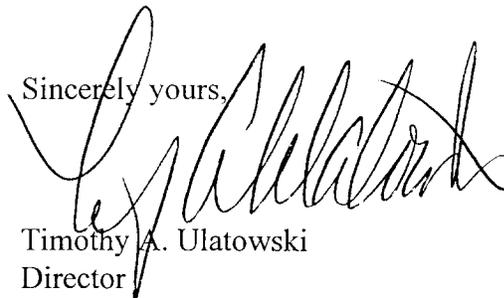
Page 2 – Dr. Winitz

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K022415

Device Name:

B.I.G™- Bone injection Gun for Pediatrics

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number _____

Prescription Use
 (Per 21 CFR 801.109)

OR

Over the Counter Use _____

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(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

8-6

510(k) Number: K022415