K080865

PYNG MEDICAL

APR 24 2008

# 510(k) Summary
(per 21 CFR 807.92)

## I. Applicant

Pyng Medical Corp.
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Richmond, BC, V6V 2E9 Canada

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Date Prepared: March 26, 2008

## II. Device Name

| | |
|---|---|
| Trade Name: | ***FAST1***™ Intraosseous Infusion System |
| Device Type: | Intraosseous Infusion System |
| Classification Name: | Hypodermic Single Lumen Needle |
| Regulation Number: | 880.5570 |
| Product Code: | FMI |
| Class: | Class II |
| Advisory Committee: | General Hospital |

## III. Predicate Devices

The ***FAST1***™ Intraosseous Infusion System (expansion of intended use population) is substantially equivalent to the ***FAST1***™ Intraosseous Infusion System cleared under K072487 and the EZ-MIO Intraosseous Infusion System from Vidacare Corporation cleared under K052195.

## IV. Intended Use of the Device

The ***FAST1***™ Intraosseous Infusion System is indicated for use in establishing a sternal intraosseous access route in adult and adolescent patients (12 years of age and older) requiring vascular administration of drugs or fluids to facilitate emergency resuscitation.

## V. Description of the Device

The ***FAST1***™ Intraosseous Infusion System has been designed to provide alternative access of the circulatory system to intravenous infusion. It utilizes intraosseous infusion in order to facilitate emergency resuscitation through the use of fluids and drugs. The device has been designed for use on the manubrium, the upper (superior) portion of the sternum.

## VI. Summary of the Technical Characteristics

The ***FAST1***™ Intraosseous Infusion System (expansion of intended use population) has the same technological characteristics as the ***FAST1***™ Intraosseous Infusion System that has received FDA 510(k) clearance under K072487.

## VII. Safety & Effectiveness

The ***FAST1***™ Intraosseous Infusion System has the same intended use and the same or similar technological characteristics as the predicate devices. The differences in technological characteristics between the modified and the predicate devices do not raise issues with the safety and effectiveness of the modified ***FAST1***™ Intraosseous Infusion System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 24 2008

Dr. Maya Butterfield
Quality Assurance and Regulatory Affairs Manager
PYNG Medical Corporation
7-13511 Crestwood Place
Richmond, B.C., V6V 2E9
CANADA

Re: K080865
Trade/Device Name: FAST1™ Intraosseous Infusion System
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: March 26, 2008
Received: March 28, 2008

Dear Dr. Butterfield:

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. 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PYNG MEDICAL

## 4. Indication for Use Statement

**510(k) Number (if known):**

**Device Name:** ***FAST1***™ Intraosseous Infusion System

**Indications for Use:**

The ***FAST1***™ Intraosseous Infusion System is indicated for use in establishing a sternal intraosseous access route in adult and adolescent patients (12 years of age and older) requiring vascular administration of drugs or fluids to facilitate emergency resuscitation.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K980865