PYNG MEDICAL

K100124

510(k) Summary
(per 21 CFR 807.92)

AUG 31 2010

I. Applicant

Pyng Medical Corp.
7 - 13511 Crestwood Place
Richmond, BC, Canada, V6V 2E9

Contact Person: Dr. Maya Butterfield
Quality Assurance & Regulatory Affairs Manager
Tel: 604.303.7964
Fax: 604.303.7987
Email: MButterfield@pyng.com

Date Prepared: June 29, 2010

II. Device Name

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

III. Predicate Devices

FASTx™ Sternal Intraosseous Device is substantially equivalent to the ***FAST1®*** Intraosseous Infusion System cleared under K080865.

IV. Indications for Use of the Device

Indications for Use:
FASTx™ Sternal Intraosseous Device 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

FASTx™ Sternal Intraosseous Device has been designed to provide an alternative to intravenous infusion access of the circulatory system. 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. The ***FASTx™ Sternal Intraosseous Device*** consists of an introducer handle with target foot which allows the user to target the recommended insertion site and place the infusion tube bone portal into the manubrium.

On withdrawing the introducer handle, the infusion tube bone portal is left firmly placed in the manubrium, the infusion tube luer lock can be connected to a source such as an IV line or standard syringe for infusion of emergency drugs or fluids.

The target foot separated from the handle is adhered to the skin over the insertion site providing protection; the infusion tube strain relief hook is clipped to the target foot for strain relief. The protective dome is placed over the target foot insertion site providing additional protection from external forces.

VI. Summary of the Technical Characteristics

FASTx™ Sternal Intraosseous Device has the similar technological characteristics as the ***FAST1®*** Intraosseous Infusion System that has received FDA 510(k) clearance under K080865.

Substantial Equivalence Table giving the similarities and differences between FASTx™ Sternal and the Predicate Device K080865

	Pyng Medical Corp.	**Pyng Medical Corp.**
Product Name	***FASTx™ Sternal Intraosseous Device***	***FAST1™*** Intraosseous Infusion System
510(k) Number	K100124	K080865
Product Code(s)	FMI	FMI
Regulation #	880.5570	880.5570
Class	II	II
Indications for Use	The ***FASTx™ Sternal Intraosseous Device*** 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.	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.
Intended User	Same as K080865	Paramedic/Doctor
Target Population	Same as K080865	Patients 12 years and older
Where Used	Same as K080865	Pre-hospital, ambulance, hospital, battlefield
IO Insertion Location	Same as K080865	Manubrium; superior part of the sternum
Method of Insertion	Same as K080865	Manual (user applied force) insertion with automatic release and automatic depth control

	Pyng Medical Corp.	Pyng Medical Corp.
Product Name	***FASTx™ Sternal Intraosseous Device***	***FAST1™*** Intraosseous Infusion System
Removal	Same as K080865	Grip infusion tubing near the surface of the skin and pull to disengage portal from cortical bone
Duration of Use	Same as K080865	Less then 24 hours. Until an alternative access is achieved
Number of Uses	Same as K080865	Single use
Sterility	Same as K080865	Delivered in sterile package
Biocompatibility	Same as K080865	Meets requirements of ISO10993
Fluids infused	Same as K080865	Emergency IV fluids
Fluids aspirated	Same as K080865	Bone marrow – optional step to check placement of Infusion Tube
Materials	Molded plastics and stainless steel	Molded plastics and stainless steel
Contra-indications	None known	None known

VII. Safety & Effectiveness

FASTx™ Sternal Intraosseous Device has the same intended use and similar technological characteristics as the predicate devices. The differences in technological characteristics between the new device and the predicate device do not raise issues of safety and effectiveness of the ***FASTx™ Sternal Intraosseous Device.***

- Bench tests, functional testing, and validation studies were conducted.
- The infusion needle tubing and portal tip of the ***FASTx™ Sternal Intraosseous Device*** are the same as the predicate device.
- The risk analysis was conducted according to ISO 14971:2007.
- Applicable biocompatibility testing was in accordance to the requirements of ISO 10993-1.
- The sterilization validation study was conducted in accordance to ISO 11137 "Sterilization of health care products – Radiation- Part2: Establishing the sterilization dose".
- Pyrogen study was conducted in accordance to USP: "Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices".
- Packaging validation was completed in accordance with ISO 11607.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pying Medical Corporation
C/O Ms. Paula Wilkerson
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

AUG 31 2010

Re: K100124
Trade/Device Name: FASTx™ Sternal Intraosseous Device
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: August 9, 2010
Received: August 16, 2010

Dear Ms. Wilkerson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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): K100124

Device Name: ***FASTx™ Sternal Intraosseous Device***

Indications for Use:

FASTx™ Sternal Intraosseous Device 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 (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

8/30/10

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

510(k) Number: K100124