April 17, 2018

Teleflex Medical
Ying Zhao
Regulatory Affairs Specialist
3015 Carrington Mill Blvd.
Morrisville, North Carolina 27560

Re: K180588
Trade/Device Name: FAST1™ Intraosseous Infusion System
FASTResponder™ Sternal Intraosseous Device
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: March 1, 2018
Received: March 6, 2018

Dear Ying Zhao:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180588

Device Name
FAST1™ Intraosseous Infusion System and FASTResponder™ Sternal Intraosseous Device

Indications for Use *(Describe)*
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.

The FASTResponder™ 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 fluid to facilitate emergency resuscitation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K180588 510(k) SUMMARY

I. SUBMITTER

Teleflex Medical, Incorporated
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Date Prepared: April 05, 2018

II. DEVICES

Trade Name:	***FAST1™*** Intraosseous Infusion System
Classification Name:	Needle, Hypodermic, Single Lumen
Product Code:	FMI
Regulation Number:	880.5570
Classification:	Class II
Review Panel:	General Hospital

Trade Name:	***FASTResponder™*** Sternal Intraosseous Device
Classification Name:	Needle, Hypodermic, Single Lumen
Product Code:	FMI
Regulation Number:	880.5570
Classification:	Class II
Review Panel:	General Hospital

III. PREDICATE DEVICES

FAST1™ Intraosseous Infusion System cleared in submission K080865

Classification Name:	Needle, Hypodermic, Single Lumen
Product Code:	FMI
Regulation Number:	880.5570
Classification:	Class II
Review Panel:	General Hospital

FASTResponder™ Sternal Intraosseous Device cleared in submission K130487

Classification Name:	Needle, Hypodermic, Single Lumen
Product Code:	FMI
Regulation Number:	880.5570
Classification:	Class II
Review Panel:	General Hospital

IV. DEVICE DESCRIPTION

The ***FAST1™*** and ***FASTResponder™*** Sternal Intraosseous Devices were designed to provide an alternative to intravenous infusion access of the circulatory system. The devices utilize intraosseous infusion to facilitate emergency resuscitation with the use of fluids and drugs. They were designed for use on the manubrium, the upper (superior) portion of the sternum.

V. 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 fluid to facilitate emergency resuscitation.

The ***FASTResponder***™ 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 fluid to facilitate emergency resuscitation.

VI. TECHNOLOGICAL CHARACTERISTICS COMPARISON TO THE PREDICATE DEVICES

This submission only affects the labeling of these products by adding contraindications to the IFUs. This submission is being submitted as "Change Being Effected" to add Contraindications due to the potential risk to public health. There were no modifications made to the ***FAST1™*** and ***FASTResponder™*** Sternal Intraosseous Devices.

Comparative Characteristics	**Predicate Device**	**Predicate Device**	**Proposed**
	FAST1™ intraosseous Infusion System K080865	***FASTResponder™*** Sternal Intraosseous Device K130487	***FAST1™*** Intraosseous Infusion System & ***FASTResponder™*** Sternal Intraosseous Device
Classification Name	Needle, Hypodermic, Single Lumen	Needle, Hypodermic, Single Lumen	Same
Product Code/ CFR	FMI, 880.5570	FMI, 880.5570	Same
Indications for Use	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 fluid to facilitate emergency resuscitation.	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 fluid to facilitate emergency resuscitation.	Same
Prescription	Yes	Yes	Same
Patient Population	For adult and adolescent patients (12 years of age and older) requiring vascular administration of drugs or fluids to facilitate emergency resuscitation.	For adult and adolescent patients (12 years of age and older) requiring vascular administration of drugs or fluids to facilitate emergency resuscitation.	Same
Contraindications	Not covered in predicate.	Not covered in predicate.	• Fracture in target bone • Excessive tissue (severe

Comparative Characteristics	Predicate Device ***FAST1™*** intraosseous Infusion System K080865	Predicate Device ***FASTResponder™*** Sternal Intraosseous Device K130487	Proposed ***FAST1™*** Intraosseous Infusion System & ***FASTResponder™*** Sternal Intraosseous Device
			obesity) and/or absence of adequate anatomical landmarks • Osteoporosis • Infection at the area of insertion • Previous, significant orthopedic procedure at the site • IO in past 48 hours of the target bone
Precautions/Warnings	Precautions Section: The ***FAST1™*** Intraosseous Infusion System is designed to penetrate 6 mm into the manubrium. Adult and adolescent* patients are expected to have a manubrium thickness greater than 6 mm. Qualified professionals should determine any appropriate or necessary exceptions, either inclusions or exclusions, to the criterion "For use with adult and adolescent* patients." Severe skin compromise such as trauma, infection or burns over the infusion site may interfere with use of the device. Check for fracture of the sternum or vascular injury which may compromise the integrity of the manubrium or its vascularization. Check for midline sternotomy scars – the device may be less effective in patients with a previous midline sternotomy. **WARNING:** Safety of the ***FAST1™*** Intraosseous Infusion System in patients with severe osteoporosis has not been proven. The ***FAST1™*** Intraosseous Infusion System is intended for use only with adult and adolescent* patients. i.e. patients 12 years of age and	Precautions Section: • The ***FASTResponder™*** is designed to penetrate 6mm into the manubrium. Qualified professionals should determine any appropriate or necessary exceptions, either inclusions or exclusions, to the criterion "for patients 12 years and older". • Proximal tip of Infusion Tube contains metal. ***The function of the device may be affected by:*** • Compromised skin over the insertion site such as trauma, infection or burns • Fracture of the sternum or vascular injury which may compromise the integrity of the manubrium or its vascularization • Midline sternotomy scars Warnings Section: • Safety in patients with very severe osteoporosis has not been proven • Insertion in sites other than the manubrium may result in ineffective infusion and/or serious injury to the patient • Reuse of ***FASTResponder™*** is not recommended due to the potential of cross-	**FAST1:** Precautions Section: The ***FAST1™*** Intraosseous Infusion System is designed to penetrate 6 mm into the manubrium. Adult and adolescent* patients are expected to have a manubrium thickness greater than 6 mm. Qualified professionals should determine any appropriate or necessary exceptions, either inclusions or exclusions, to the criterion "For use with adult and adolescent* patients." The ***FAST1™*** Intraosseous Infusion System is intended for use only with adult and adolescent* patients. i.e. patients 12 years of age and older. The ***FAST1™*** is not to be left in situ for more than 24 hours. **DESIGNATED INSERTION SITE:** The single designated site of insertion is the adult and adolescent* manubrium, on the midline and 1.5 cm (5/8 inch) below (inferior to) the supra-sternal notch (sternal notch). Proper placement of the Patch helps ensure insertion at this site. **WARNING:** Insertion of the FAST1™ Intraosseous Infusion System in sites other than the manubrium may result in ineffective infusion and may result in overpenetration of the Infusion

Comparative Characteristics	Predicate Device ***FAST1™*** intraosseous Infusion System K080865	Predicate Device ***FASTResponder™*** Sternal Intraosseous Device K130487	Proposed ***FAST1™*** Intraosseous Infusion System & ***FASTResponder™*** Sternal Intraosseous Device
	older. The ***FAST1™*** is not intended to be left in situ for more than 24 hours. **DESIGNATED INSERTION SITE:** The single designated site of insertion is the adult and adolescent* manubrium, on the midline and 1.5 cm (5/8 inch) below (inferior to) the supra-sternal notch (sternal notch). Proper placement of the Patch helps ensure insertion at this site. **WARNING:** Insertion of the FAST1™ Intraosseous Infusion System in sites other than the manubrium may result in ineffective infusion and may result in overpenetration of the Infusion Tube with consequent serious injury to the patient.	contamination, which may lead to serious injury or death. The ***FASTResponder™*** is unlikely to function after use. • Do not insert finger(s) in the open end of the device due to the potential of needle stick.	Tube with consequent serious injury or death to the patient. **FASTR:** Precautions Section: • The ***FASTResponder™*** is designed to penetrate 6mm into the manubrium. Qualified professionals should determine any appropriate or necessary exceptions, either inclusions or exclusions, to the criterion "for patients 12 years and older". • Proximal tip of Infusion Tube contains metal. • The ***FASTResponder™*** is not to be left in situ for more than 24 hours. Warnings Section: • Insertion in sites other than the manubrium may result in ineffective infusion and/or serious injury or death to the patient. • Single use: Do not reuse, reprocess or re-sterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality. • Do not insert finger(s) in the open end of the device due to the potential of needle stick.
IO Insertion site	Sternum	Sternum	Same
Method of Insertion	Manual insertion	Manual insertion	Same
Duration of Use	Less than 24 hours	Less than 24 hours	Same
Number of Uses	Single use	Single use	Same
Sterilization Method	Radiation	Radiation	Same
Sterility Assurance level (SAL)	10^{-6}	10^{-6}	Same
Materials	Molded plastics and stainless steel	Molded plastics and stainless steel	Same

VII. PERFORMANCE DATA

No performance testing was needed to support this change.

VIII. CONCLUSIONS

The proposed devices are substantially equivalent to the predicate devices.