

11.0 510(K) SUMMARY

510(K) SUMMARY APR 25 1997

This summary of **safety and effectiveness** was prepared on January 31, 1997 and is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

Submitted by:

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Names of Device:

Trade Name: F.A.S.T. 1™ Intraosseous Infusion System
Common Name: Intraosseous Infusion System (Hypodermic Needle)
Classification Name: Hypodermic Single Lumen Needle (880.5570)
Class: II
Panel: 80
Procode: FMI - Hypodermic Single Lumen Needle

Predicate Devices:

The legally marketed devices (predicate devices) upon which substantial equivalence to the F.A.S.T. 1™ Intraosseous Infusion System is based are:

1. "COOK Intraosseous Infusion Needles". The Cook, Inc. SUR-FAST® Intraosseous Infusion Needle Set and Components, and the Cook Disposable Intraosseous Infusion Needles. The 510(k) numbers for these products are K913258 and K915409.
2. "SHERWOOD ILLINOIS needle". Sherwood Medical Co. Monoject® 16 gage Illinois Sternal / Iliac Aspiration Needle, reorder number 8881-245164. The 510(k) number for this product is K883014.

Description of Device:

The F.A.S.T. 1™ Intraosseous Infusion System has been designed to provide a means, as an alternative to intravenous infusion, for facilitating emergency resuscitation of adults through the administration of fluids and drugs. The F.A.S.T. 1™ Intraosseous Infusion System has been designed for use on the adult sternum. It consists of a primary component - the infusion tube, and secondary components - the introducer for placing it through the skin into the sternum of the patient, the target / strain-relief patch, and a protector dome. There is also an infusion tube removal tool.

Function, concepts, performance characteristics:

The concept of the device is that it will allow relatively untrained and unpractised users to safely and effectively insert a flexible infusion needle into the adult sternum.

The F.A.S.T. 1™ Intraosseous Infusion System is a hand-held, manually operated passive device, (it has no internal energy source). The infusion needle has a sharp stainless steel tip, a flexible shaft and a standard Luer connector. The user grasps an introducer handle attached to the infusion needle, and pushes the needle tip through the skin and overlying tissue into the sternum of the subject. Fluids or drugs are delivered through the needle to the marrow space of the sternum, and flow out the emissary veins of the sternum into the central circulation.

When the user has pushed the infusion needle to the correct penetration depth in the sternum, a mechanism inside the introducer handle disconnects the handle from the infusion needle, preventing the user from pushing the needle any further. The mechanism is fast acting - the user can push the needle in, have it released at the correct depth, and remove the introducer handle, all in the space of 1-2 seconds. The principle of the mechanism is that it detects the position of the anterior surface of the cortical bone of the sternum, and relates the position of the tip of the infusion needle to the surface of the cortical bone.

Another feature of the device is an adhesive patch which is applied to the top of the patient's chest. During application the user aligns the patch with the supra-sternal notch. The position of the recommended insertion site is marked on the patch to aid in landmarking. Also, the patch and an associated cover provide protection and strain-relief to the site and the installed infusion needle.

The materials used in the F.A.S.T. 1™ Intraosseous Infusion System are materials commonly used in other infusion devices; stainless steels, medical

grade polyurethane and PVC, radiation sterilizable medical grade plastic (polyetherimide), and patch and adhesive materials commonly used in mounting transdermal drug delivery devices to human skin for extended periods.

Intended Use of the Device:

The F.A.S.T. 1™ Intraosseous Infusion System is intended for intraosseous infusion as an alternative to intravenous access to facilitate emergency resuscitation through the use of drugs and fluids.

Technological Characteristics compared with Predicate Devices:

The F.A.S.T. 1™ Intraosseous Infusion System and the COOK needles and the SHERWOOD needle have common technological characteristics in that they:

- are passive, hollow entry ports for the delivery of fluids to a marrow space;
- have a stainless steel tip which penetrates through skin and overlying tissue into a marrow space;
- are manually inserted using forces applied by the practitioner to a plastic handle, at least part of which is removable;
- penetrate the cortical bone by the user pushing on the stainless steel tip, either without twisting (Pyng) or with twisting (Cook, Sherwood);
- have a lumen which may be blocked with a removable stylet during insertion;
- have a lumen which conveys drugs or fluids to a tip positioned in a marrow space;
- include a distal connector which is a Luer taper connector and which connects to the source of drugs or fluids;
- are supplied as biocompatible, sterile, single-use products;
- insert a needle or portal which is removed by attaching a remover and/or twisting and pulling out.

Each of the F.A.S.T. 1™ Intraosseous Infusion System, the COOK needles and the SHERWOOD needle consists of an apparatus and method for placing, into the marrow space of a bone, a hollow tube with a Luer connector on the distal end, for the purpose of delivering drugs and fluids. Each is manually operated. Each is made of common biocompatible steels and plastics.

Not all the technological characteristics of the F.A.S.T. 1™ Intraosseous Infusion System are the same as the predicate devices. The new technological characteristics of the F.A.S.T. 1™ Intraosseous Infusion System all arise from

the fundamental design objective of producing a system which is fully compatible with the environment in which it will be used. The F.A.S.T. 1™ Intraosseous Infusion System has several new technological characteristics.

Tests conducted:

Data have been obtained from tests conducted by or for P yng Medical Corp., and from published literature. These tests relate to the safety and effectiveness of the new technological characteristics, and of technological characteristics shared with the predicate devices. The data include material on biocompatibility, material relating to technological characteristics shared with the predicate devices, and material relating to new technological characteristics.

These data support the assertion that the F.A.S.T. 1™ Intraosseous Infusion System is as safe and as effective as the predicate devices.

Non-clinical data, simulated clinical trials, simulations and simulators - general description:

The data include the results of common non-clinical engineering tests — masses, forces, strengths, etc. In addition, much data was acquired during testing with excised human sternums, with human cadavers, and with live human subjects in a variety of simulations and simulated clinical trials.

In order to appropriately evaluate and develop the F.A.S.T. 1™ Intraosseous Infusion System, P yng developed two different mechanical devices as simulators - a simulated Intraosseous Infusion System, and a simulated sternum. These devices allowed the developers, and potential users, to experience the use of the system on live human volunteers without injury to the volunteers, and to experience insertion and placement of infusion portals at the correct depth through overlying layers of tissue and skin. Using these devices, simulated clinical trials were conducted by civilian and military paramedics.

Further data on the performance of the complete F.A.S.T. 1™ Intraosseous Infusion System were gathered from testing with human cadavers and excised sternums.

How the test results support substantial equivalence:

The F.A.S.T. 1™ Intraosseous Infusion System and predicate devices meet the relevant voluntary and mandatory standards including those for biocompatibility

(ISO 10993-1 as modified in FDA General Program memorandum #G95-1), sterilization (ANSI/ISO 11137 (R2-94)), and mechanical performance of Luer connectors (ISO 594).

The F.A.S.T. 1™ Intraosseous Infusion System has passed evaluation of all the internal specifications developed by P yng Medical Corp. to ensure that the infusion system meets or exceeds the performance of the predicate devices, and meets or exceeds the safety and effectiveness requirements for a successful adult emergency intraosseous infusion system. The F.A.S.T. 1™ Intraosseous Infusion System has been evaluated by both civilian and military paramedics, and given highly positive ratings. To achieve this level of performance certain technological features not common to the predicate devices had to be developed and incorporated.

Safety. The quick push-pull insertion method, the protector dome, and the strain-relief and target functions of the target patch ensure that safe use of the system requires only the skills possessed by the intended user. The protector dome keeps the infusion site clean, and allows the user to see the site during infusion. The depth control mechanism, the bone probe and the target function of the patch avoid excess penetration. The flexible needle and subcutaneous portal, and the strain relief function of the patch minimize leakage. Data included in the submission support these assertions and the conclusion that the F.A.S.T. 1™ Intraosseous Infusion System is as safe as the predicate devices.

Effectiveness. The target function of the patch facilitates correct placement at the recommended insertion site. The depth control mechanism and the bone probe ensure that the system penetrates into the marrow space. These features together with the push-pull insertion method ensure that the system meets user criteria for vascular access time and success rate. The strain-relief function of the patch resists pull-out resulting from tension on the infusion line. The flexible needle and subcutaneous portal, and the protector dome, ensure that the system will be unaffected by large external forces and be compatible with other procedures performed on the patient. Data included in the submission support these assertions and the conclusion that the F.A.S.T. 1™ Intraosseous Infusion System is as effective as the predicate devices.

Conclusions:

The F.A.S.T. 1™ Intraosseous Infusion System and the predicate devices are all indicated for use in intraosseous infusion.

The F.A.S.T. 1™ Intraosseous Infusion System and one or both of its predicate devices are similar in that they are passive, needle-like devices intended for

emergency intraosseous infusion. They have a handle, at least part of which is removable, which the care-giver uses to place a steel tip through overlying tissue into the marrow space of a bone, using pushing and/or twisting motions. They have a lumen with a distal Luer taper connector which connects to a source of drugs or fluids to be infused. They are removed by attaching a remover and/or twisting and pulling out. They are supplied as biocompatible, sterile, single use products.

The above data and conclusions demonstrate that the F.A.S.T. 1™ Intraosseous Infusion System is as safe and effective as the predicate devices.