Attachment A: Revised

MAR 2 6 2004

Luther Needlesafe Products, Inc.
3199 Airport Loop Drive, Unit E
Costa Mesa, CA 92626
Phone 714-434-4561 FAX 714-434-1557

510(k) Summary

Submitted by:

Luther Needlesafe Products, Inc.
3199 Airport Loop Drive, Unit E
Costa Mesa, California 92626-3414
Phone: 714-434-1564
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Contact Person:

Greg Holland
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606
Phone: 949-262-0411
Fax 949-552-2821

Device Name:

Classification Name:	Set, Administration, Intravascular
Classification:	Class II
Product Code:	FPA
Regulation Number:	21 CFR 880.5440
Proprietary Name:	Luther Safety Huber Needle Set
Common Name:	Safety Huber Needle and Administration Set

Predicate Device:

Luther Safety Huber Needle Set
K021565

Device Description:

The Luther Safety Huber Needle Set is a standard right angle Huber needle and administration set with a needlestick prevention feature, designed for use with a vascular access infusion system. It is manufactured with conventional medical grade, biocompatible materials. The Luther Safety Huber Needle Set operates as a standard Huber needle with the addition of a safety feature to aid in the prevention of needlestick injuries to the health practitioner.

It is supplied sterile for single use only.

Indications for Use:

The Luther Safety Huber Needle Set is a device intended to administer drugs to a patient from a container through a subcutaneous implanted port. The Huber Needle safety needle cover is manually activated during removal. When the safety feature is activated, the device is designed to aid in the prevention of accidental needle sticks.

Summary of the technological characteristics of this device compared to the predicate, original, device:

The old and the new design have similar technological characteristics and are equivalent.

There is no change in the following items:

Indications for Use
Patient contact or fluid path materials
Safety activation feature
Instructions for Use
Sizes and options for gauge, length and needless Y site

There are changes in following items:

Overall height of device is lower
Clear body of device allows user to check insertion

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 26 2004

Luther Needlesafe Products, Incorporated
C/O Mr. Greg Holland
Consultant
Regulatory Specialist, Incorporated
3722 Avenue Sausalito
Irvine, California 92606

Re: K040527
Trade/Device Name: Low Profile Luther Safety Huber
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: February 27, 2004
Received: March 1, 2004

Dear Mr. Holland:

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 (301) 594-5618. 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/dsma/dsmamain.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

510(k) Number (if known): K040527

Device Name: Low Profile Luther Safety Huber

Indications For Use:

Intended to administer drugs to a patient from a container through a subcutaneous implanted port. The Huber Needle safety needle cover is manually activated. When the safety feature is activated, the device is designed to aid in the prevention of accidental needle sticks.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Vicki Holland for Anthony Watson, B.C.

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

510(k) Number: K040527