Attachment E – 510(k) Summary

K021565

510(k) Summary

NOV 14 2002

Submitted by: Luther Research Partners LLC
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:

Millennium Huber Plus Safety Infusion Set
K993848

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. When the safety feature is activated, the device is designed to aid in the prevention of accidental needle sticks.

Performance Data:

Information was supplied to support substantial equivalence to the predicate device. Part of this support was a simulated use clinical trial in which 692 Luther Safety Huber Needle Sets were used resulting in no incidences of sharps injury or incidences where the safety feature failed to activate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 14 2002

Luther Research Partners, LLC
C/O Mr. Greg Holland
Regulatory Specialist, Incorporated
3722 Avenue Sausalito
Irvine, California 92606

Re: K021565
Trade/Device Name: Luther Safety Huber Needle Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA and LJS
Dated: September 16, 2002
Received: September 16, 2002

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.

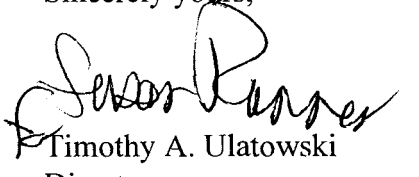
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment D – Revised Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K021565

Device Name: Luther Safety Huber Needle Set

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. When the safety feature is activated, the device is designed to aid in the prevention of accidental needle sticks.

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

510(k) Number: K021565

(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)