510(k) SUMMARY

Submitted by:	Luth-All Medical Products, LLC 3199 Airport Loop Drive, Unit E Costa Mesa, CA 92656 (949) 434-1564 Phone (949) 434-1557 FAX
Contact Person:	Shepard G. Bentley Synergy Biomedical, LLC 28202 Cabot Road, Suite 300 Laguna Niguel, CA 92677 (949) 365-5790 Phone (949) 365-5791 FAX E:Mail sbentley@synergybiomed.com
Date Prepared:	27 September 2004
Device Name:	Luth-All Safety Sub-Q Needle Set
Trade Name:	Luth-All Safety Sub-Q Needle Set
CommonName:	Safety Needle and Administration Set
Classification Name:	Set, Administration, Intravascular
Device Class:	II (two)
Procode:	FPA
CFR Reference:	880.5440
Predicate Device #1:	Luther Safety Huber Needle Set
Predicate 510(k) #1:	K021565
Predicate Device #2:	"Evans Sub-Q" (Catalog # 4206)
Predicate 510(k) #2:	K020530
Device Description:	The Luth-All Safety Sub-Q Needle Set is a 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. It operates as a standard safety needle with the addition of a built in active safety feature, which when activated the device is designed to aid in reducing the possibility of accidental needle sticks. It is supplied sterile for single use only.
Indications for Use:	The Luth-All Safety Sub-Q Needle Set is a device intended to administer drugs to a patient from a container by infusion subcutaneously. It operates as a standard safety needle with the addition of a built in active safety feature, which when

activated the device is designed to aid in reducing the possibility of accidental needle sticks.

Intended Use: The device intended to be used only by trained personnel to administer drugs to a patient from a container by infusion subcutaneously. Typical use would be for example to administer Insulin. The needle is placed subcutaneously during therapy. After the needle placement, the device is connected to a syringe or other delivery devices, via a standard luer connection, to administer the drugs. When the infusion is completed, the device is removed by activating the safety feature, and discarded according to the appropriate disposal procedure for the health provider.

Technological Comparison: A summary of the technological characteristics of this device compared to the predicate device can be seen in the Comparison Table in the Specifications Section. This device and the predicate have similar technological characteristics and are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2004

Luth-All Medical Products, LLC
C/O Mr. Shepard G. Bentley
Regulatory Consultant
Synergy Biomedical, LLC
28202 Cabot Road, Suite 300
Laguna Niguel, California 92677

Re: K042666
Trade/Device Name: Luth-All Safety Sub-Q Needle Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: November 12, 2004
Received: November15, 2004

Dear Mr. Bentley:

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 (240) 276-0115. 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

Indications for Use

510(k) Number (if known): K042666

Device Name: Luth-All Safety Sub-Q Needle Set

Indications for Use:

The Luth-All Safety Sub-Q Needle Set is a device intended to administer drugs to a patient from a container by infusion subcutaneously. It is manufactured with conventional medical grade, biocompatible materials. It operates as a standard safety needle with the addition of a built in active safety feature, which when activated the device is designed to aid in reducing the possibility of accidental needle sticks.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K042666