K032934

NOV 1 3 2003

# 510(k) Summary of Safety and Effectiveness



1 Submitter:

**MPS Acacia**
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Brea, CA 92821
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2 Contact:

Fergie F. Ferguson, RA/QA Manager
MPS Acacia

3 Date prepared: October 30, 2003

4 Device trade name: MPS Acacia Safeguard Huber Device

Common name: Set, Administration, Intravascular

5 Predicate device: MPS Acacia Huber Needle Extension Set
510(k) number: K982047
Marketed by: MPS Acacia
499 Nibus St., Suite E
Brea, CA 92821

Predicate device: Millennium Huber Plus Safety Infusion Set
510(k) number: K993848
Marketed by: Millennium Medical (Aka Now Medical)
696 Unionville Road, Suite 6
Kennett Square, PA 19348

Predicate device: Luther Safety Huber Needle Set
510(k) number: K021565
Marketed by: Luther Research Partners
3199 Airport Loop Drive, Unit E
Costa Mesa, CA 92626

Predicate device: Lifeguard Safety Infusion Set
510(k) number: K013871
Marketed by: Horizon Medical Products
One Horizon Way
Manchester, CA 31816

6 Description:

6.1 The MPS Safeguard Huber Device is a family of sterile and non-pyrogenic devices used for transdermal infusion via subcutaneous access ports. These devices consist of angled non-coring stainless steel needle bonded to infusion tubing ending with a standard female luer lock connector. Each set is provided with a needle tip protector, and luer cap. Various configurations may also include Y-injections sites, needleless injection sites, and clamps associated with standard tubing infusion sets.

6.2 The MPS Acacia Safeguard Huber Device is designed to allow the clinician to activate a trigger on the device that will deploy a protective sheath to cover the entire needle once the device is removed from the patient. The device is designed to help minimize accidental needlestick injuries.

7 Intended Use:

The **MPS Acacia Safeguard Huber Device** is intended: a) for use with implanted infusion ports for continuous or intermittent infusion therapy; and b) for infusion or withdrawal of I.V. fluids, blood, blood products, and drugs. The **MPS Acacia Safeguard Huber Device** should be changed per CDC guidelines or per hospital protocol.

8 Technological comparison to predicate device:

8.1 The MPS Acacia Safeguard Huber Device offers identical technique, usage parameters and intended use to the predicate devices except for the needle cover safety mechanism.

9 Sterility:

9.1 The sterilization of the MPS Acacia Safeguard Huber Device meets the requirements per the FDA's "Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA ODE 361, August 30, 2002", and the "ORDB 510(k) Sterility Review Guidance ODE/DGRND/ORDB 659, September 3, 1997."

9.2 The sterilization method that will be used to sterilize the MPS Acacia Safeguard Huber Device will be ethylene oxide (EO).

9.3 The method used to validate the sterilization cycle is AAMI/ANSI/ISO 11135-1994.

9.4 The packaging used to maintain the device's sterility is a vented sterile barrier pouch comprised of gas penetrable lid stock heat sealed to a clear film such as Mylar of polyethylene.

9.5 The maximum residual level for EO is 25ppm, for ECH is 25ppm, and for EG is 250ppm.

9.6 The MPS Acacia Safeguard Huber Device will be labeled "Non-Pyrogenic." The method used to make the determination is by limulus amebocyte lysate (LAL) testing.

9.7 The sterility assurance level (SAL) will be a minimum of $10^{-6}$.

9.8 The direct and indirect patient fluid contacting components of the MPS Acacia Safeguard Huber Device are manufactured of identical material to the MPS Acacia Huber Needle Extension Set, 510(k) number K982047, as listed in the predicate devices above. There are no differences in sterility challenges between the two devices since the configurations are the same. An evaluation was performed to determine that both the density and microbial challenge devices used in the sterilization validation were more difficult to sterilize than the Safeguard Huber Device. The density challenge device filled in a sterilization container weighed approximately 25 pounds in comparison to approximately 20 pounds for the Safeguard Huber Device. The microbial challenge device use in the sterilization validation has a more tortuous fluid pathway (more difficult for the sterilant to reach the entire area) than the Safeguard Huber Device. The Microbial challenge device contains a biological indicator that has a spore population of $3.0 \times 10^{6}$. The microbial challenge device is loaded into locations within the density challenge devices during the validation. The complete

extermination of the spore population during the validation ensures a $10^{-6}$ sterility assurance level.

10 Biocompatibility:

10.1 The direct and indirect patient fluid contacting components of the MPS Acacia Safeguard Huber Device are manufactured of identical material to the MPS Acacia Huber Needle Extension Set, 510(k) number K982047, as listed in the predicate devices above.

10.2 Biocompatibility testing has been performed for all of the materials used in the manufacture of the MPS Acacia Huber Needle Extension Set based on ISO 10993-1 and FDA G95-1 guidelines.

10.3 The processing of the material in the manufacturing and sterilization process is the same for both the MPS Acacia Safeguard Huber Device and the substantially equivalent MPS Acacia Huber Needle Extension Set.

10.4 The following tests were performed:

10.4.1 Cytotoxicity (MEM Elution)
10.4.2 Sensitization (Guinea Pig Maximization Sensitization)
10.4.3 Irritation (Intracutaneous Reactivity)
10.4.4 Systemic Toxicity (Acute Systemic Toxicity)
10.4.5 Hemocompatibility (Hemolysis – Extract Method)

10.5 All tests concluded the materials to be biocompatible for their intended purpose. There are no latex materials contained in the Safeguard Huber Device and there were no latex components tested during the biocompatibility evaluation.

11 Simulated Clinical Testing:

11.1 A simulated clinical study was performed by Registered Nurses (RN) on 3,000 units.

11.2 The study was performed in accordance with the FDA's "Supplementary Guidance on Premarket Notifications for Medical Devices with Sharps Injury Prevention Features; Guidance for Industry and FDA."

11.3 There were no safety feature activation or deactivation failures that occurred during the testing of the 3000 units. The ability to activate and not to deactivate the safety mechanism are the two most important features that must not fail during use.

11.4 There were no other failures that occurred during the simulated clinical testing.

12 Non-clinical test summary:

12.1 Bench testing was performed to insure that the Safeguard Huber Device meets the product specifications as developed by MPS Acacia.

13 Data Documentation

13.1 All in-house and external lab test results and data analysis/documentation for the MPS Acacia Safeguard Huber Device, confirming items number 9 through 12 through current and past testing, are maintained in a secure manner at MPS Acacia in Brea, CA 92821. These in-house and external lab test results and data analysis/documentation, detailing the FDA and ISO acceptable criteria and standards for this proposed premarket notification clearance of the MPS Acacia Safeguard Huber Device, are available upon request and/or official inspection by any authorized agent of the U.S Food and Drug Administration.

14 Conclusion:

14.1 The MPS Acacia Safeguard Huber Device is substantially equivalent to the products currently being legally marketed by MPS Acacia, Millennium Medical (Aka Now Medical), Luther Research Partners, and Horizon Medical Products. Below is a substantial equivalence comparison table between the MPS Acacia Safeguard Huber Device and the predicate devices, as listed:

| **Category** | **MPS Acacia** Safeguard Huber Device | **MPS Acacia** Huber Needle Extension Set | **Millennium Medical (Aka Now Medical) -** Millennium Huber Plus Safety Infusion Set | **Luther Research Partners -** Luther Safety Huber Needle Set | **Horizon Medical Products -** Lifeguard Safety Infusion Set |
|---|---|---|---|---|---|
| 510(k) Number | | K982047 | K993848 | K021565 | K013871 |
| Intended Use | 1. The MPS Acacia Safeguard Huber Device is intended for use with implanted infusion ports for continuous or intermittent infusion therapy. 2. For infusion or withdrawal of I.V. fluids, blood, blood products, and drugs. 3. The Safeguard Huber Device has a manually activated sheath that covers the needle once it is removed from the patient. The sheath will help minimize accidental needlestick injuries. 4. Change per CDC guidelines or per hospital protocol. | 1. The MPS Acacia Huber Needle Extension Set is intended for use with implanted infusion ports for continuous or intermittent infusion therapy. 2. For infusion or withdrawal of I.V. fluids, blood, blood products, and drugs. 3. Change per CDC guidelines or per hospital protocol. | The Millennium Huber Plus Safety Infusion Set is a Safety IV administration set with a non-coring, ninety-degree, right-angle Huber needle, used to access surgically implanted vascular ports. The Huber needle is used to administer fluids or to withdrawal blood. The Huber Plus system facilitates safe removal of the needle by encapsulating the needle within the attachment wings to help prevent needlestick injuries when using the device for vascular port access. | 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. | The Lifeguard Safety Infusion Set is used to access implanted vascular ports to administer fluids and/or to withdrawal blood. The Lifeguard Safety Infusion Set facilitates safe removal of the needle by encapsulating the needle during port de-accessing to help prevent needlestick injuries. |
| Tubing | Non-DEHP PVC | Same | Similar | Similar | Same |
| Needle | 90° non-coring medical grade stainless steel. | Same | Same | Same | Same |
| Sterility | Sterile and non-pyrogenic. | Same | Same | Same | Same |

| | | | | | |
|---|---|---|---|---|---|
| Packaging | Vented sterile barrier pouch or formed tray comprised of a gas penetrable lid stock heat sealed to a clear film such as Mylar or formed PE. | Same | Same | Same | Same |

14.2 The following guidance documents were used in the testing performed within sections numbers 9 through 12:

14.2.1 **Sterilization validation** – The sterilization process was validated and monitored per AAMI/ANSI/ISO 11135-1994, Method C.

14.2.2 **Biocompatibility** – Biocompatibility testing was performed per ISO 10993-1 and FDA G95-1, External Communicating Devices, Blood Path Indirect, Contact Duration B (>24 hours to ≤30 days).

14.2.3 **Simulated Clinical Testing** – Simulated clinical testing was performed in accordance to the FDA's "Supplementary Guidance on Premarket Notifications for Medical Devices with Sharps Injury Prevention Features; Guidance for Industry and FDA; issued: December 31, 2002 ."

14.2.4 **Bench Testing** – Bench testing was performed in accordance with product specifications developed in-house by MPS Acacia.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2003

MPS Acacia
C/O Dr. Alfredo J. Quattrone
Responsible Third Party Official
California Department of Health Services
Food & Drug Branch
P.O. Box 942732 (MS-357)
Sacramento, California 94234-7320

Re: K032934
Trade/Device Name: MPS Acacia Safeguard Huber Device
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 28, 2003
Received: October 29, 2003

Dear Dr. Quattrone:

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.

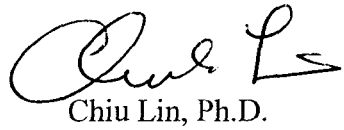
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4618. 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):** K032934

**Device Name:** MPS Acacia Safeguard Huber Device

**Indications For Use:**

The **MPS Acacia Safeguard Huber Device** is intended: a) for use with implanted infusion ports for continuous or intermittent infusion therapy; and b) for infusion or withdrawal of I.V. fluids, blood, blood products, and drugs. The **MPS Acacia Safeguard Huber Device** should be changed per CDC guidelines or per hospital protocol.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cascante

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

510(k) Number: K032934

Prescription Use (Per 21 CFR 801.109) or Over-The-Counter Use _____

(Optional Format 1-2-96)