K973497

JAN 13 1998

(I) 510(k) Summary:

This summary is submitted in conformance with the format described in the 21 CFR Part 807.92 interim rule dated April 28, 1992.

(1) Submitted By:

MedCare Medical Group, Inc.
234 Old Homestead Highway
E. Swanzey, NH 03446

Contact Person:

Craig J. Bell
Director of Research and Development
(603)352-3230

(2) Name of Device:

HuberLoc™

Classification Name:

Unknown

(3) Identification of Predicate Devices:

510(k) Number K955748
Doyle Extractor
Product Code: MSDX-12
Med Stream Medical, Inc.
Streetsboro, OH 44241

(4) Description of Device Subject to Premarket Notification:

The MedCare Medical Group's HuberLoc is a device designed to assist in the removal and containment of Huber needles. The device consists of three plastic molded components; an inner slide and an outer housing, right and left halves. The HuberLoc is slid over the Huber needle, so the needle cannula is in the slot of the forks. Pressure is applied to the top of the HuberLoc to support the skin and the infusion port with your thumb. The first and middle finger of the same hand pull on the wings of the inner slide, in opposition to the thumb pressure. This action removes the Huber needle and draws it into the outer housing. The inner slide locks into place and contains the needle.

the outer housing. The inner slide locks into place and contains the needle. The operation utilizes an easy one handed technique. This eliminates any rebound reflex. The HuberLoc is provided sterile, disposable, and for single patient use.

(5) Intended Use of the Device:

The HuberLoc is a single patient, single use, disposable device which is intended to assist in the procedure of removing Huber needles.

(6) Technological Characteristics

The HuberLoc provides a device that can reduce the potential of an inadvertent needle stick from the removal of a Huber needle. The HuberLoc eliminates the use of a stabilizing hand and the rebound reflex. The HuberLoc relies on a mechanical removal of the Huber needle and a containment means once the Huber needle is removed. The predicate device assists in the removal, but does not contain the removed contaminated sharps.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 1998

Mr. Craig J. Bell
Director of Research and Development
MedCare Medical Group, Incorporated
234 Old Homestead Highway, Route 32
East Swanzey, New Hampshire 03466

Re: K973497
Trade Name: HuberLoc™ Needle Removal & Containment Device
Regulatory Class: Unclassified
Product Code: LJT
Dated: November 13, 1997
Received: November 14, 1997

Dear Mr. Bell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

(J) **Indications For Use Statement**

510(k) Number (if known): K973497

Device Name: HuberLoc™

Indications For Use:

The intended use of this device is for the removal of 90° winged infusion sets, THE GRIPPER™, and VasTack™, having a 1-1/2" needle or shorter from implanted ports and the containment of the used needle until placed in a sharps container.

(THE GRIPPER is a trademark of SIMS Deltec and VasTack is a trademark of Gish Biomedical.)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rebecca Cucenka

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973497

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)