MAR 3 1 2006

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510(K) SUMMARY

FOI RELEASABLE

Pursuant to § 513(i)(3)(A) of the Food, Drug, and Cosmetic Act, One Stick is required to submit with this Premarket Notification "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." One Stick chooses to submit a summary of information respecting safety and effectiveness.

Classification Name:	Intravascular Administration Set and Extension Set (includes needle less access devices/systems and blood flow regulators)
Common/Usual Name:	Intravascular Administration Set
Proprietary Name:	One Stick™ Y Extentsion Set and Volumeter™
Device Classification:	Class II

Name	Number	21 CFR Ref.
Intravascular Admin Set Subcutaneous, Intravascular	FPA	§ 880.5440

Owner/Operator: One Stick LLC
P.O. Box 3575
Lubbock, Texas 79452-3575
(806) 842-3999

Contact Person: Tracy Magee, Vice President

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DESCRIPTION OF DEVICE

One Stick™ Volumeters™ and Y-Set family of sets are supplied as sterile devices, and are intended for single patient use only. They are available in 3cc and 5cc sizes and are manufactured per cGMP Standards. The Y sets are comprised of standard components currently on the market. The Y sets are currently covered by 510(k) K051499. The barrel of the Volumeter™ is currently marketed by Becton Dickinson in their 3ml syringe. The Vent cap is molded with Class VI polypropylene, silicone O-ring and a Gore expanded PTFE supported membrane.

INDICATIONS FOR USE

The One Stick™ Volumeters™ and Y-Set families are indicated for the collection and handling of blood specimens prior to further testing.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

The One Stick™ Device is a blood collection assistance device for drawing samples from patients with suboptimal blood flow for standard procedures (Elderly and pediatric patients, those patients that may experience blood vessel collapse or excessive hemolysis when conventional Vacutainers are used directly). The device consists of a male luer fitting for attaching to a venipuncture, a section of tubing connecting the luer to a Y-Connector with a Roberts clamp for interrupting flow, two additional sections of tubing attached to needless access devices. This Y device is then attached to a vented volume collection tube.

The Y set or device was approved under 510(k) K051499 to Medegen Medical Manufacturing Services. In our case these devices are being produced by Medegen for One Stick. The barrel of the Volumeter is produced by BD and is molded from their standard tooling.

PERFORMANCE CHARACTERISTICS

The results of these test show that when the devices are built to specifications they all function as expected. Detailed results can be found in engineering reports dated July 13th and August 17th 2005.

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CONCLUSION

One Stick believes that the One Stick™ Blood collection assistance device is substantially equivalent to the currently marketed Intravascular Administration Set by Medegen Medical Manufacturing Services 510(k) K051499. A comparison of the descriptive characteristics of these products demonstrate the One Stick Blood collection assistance device is equivalent in its indications for use, while being very similar in design and materials. In addition, One Stick has presented laboratory testing and biocompatibility information. The information presented provides assurance that the One Stick Blood collection assistance device will meet the minimum requirements that are considered acceptable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2006

One Stick Limited Liability Company
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, Limited Liability Company
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K060672
Trade/Device Name: One Stick™ Y Extension Set and Volumeter™
Regulation Number: 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product Code: FPA
Dated: March 10, 2006
Received: March 14, 2006

Dear Mr. Job:

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 (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 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.

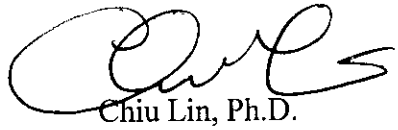
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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 continue 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 Dental, Anesthesiology, General
Hospital, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

K060672

510(k) Number (if known):

Device Name: One Stick™ Y Extension Set and Volumeter™

Indications For Use:

ARE INDICATED FOR THE COLLECTION AND HANDLING OF WHOLE BLOOD SPECIMENS PRIOR TO FURTHER TESTING

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

[illegible] General Hosp[illegible]
[illegible] Dental Devices

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