510K Summary Letter

JUN 12 2009

February 10, 2009

Food and Drug Administration
Center for Devices and Radiological Health
510K Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

RE: Traditional 510 (K) Submission

Dear Madam/Sir:

In accordance with Section 510 (K) of the U.S. Food, Drug and Cosmetic Act (21 U.S.C. 301), Myco Medical Supplies, Inc. ("Myco Medical, Inc.") hereby submits a premarket notification for **VAKU-8™** Brand Sterile Multi Sample Blood Collection Needle. The reason for the 510 (K) is that **VAKU-8™** brand Blood Collection Needles are a new device to the US Market.

42 Fed. Reg. 807.87 Required Information

1. Submitter Information

Manufacturer Name:
Hindustan Syringes And Medical Devices LTD.
FDA Registeration No:
8040227

Contact Person of the Submission:
Sam Kumar
MYCO Medical Supplies, Inc.
158 Towerview Ct.
Cary, NC
USA, 27513
Phone:919-4602535 Ext-105
Fax: 919-460 2536
Email: skumar@mycomedical.com

2. Establishment

Myco Medical Supplies Inc.'s
Owner/Operator # is 9007658
Registration # : 1058382.

3. Classification Information

a) **Product:** Sterile Multi Sample Blood Collection Needle.
b) **Trade Name: VAKU-8™** Blood Collection Needle

c) **Device Common Name:** Blood Collection Needle
d) Class II device
e) **Regulation No:** 880.5570
f) **Classification Panel and Product Code:** FMI

4. **Section 514 Requirements**
No action is required to comply with requirements of the act under Section 514.

5. **Predicate Device**
510K K992699
Trade Name:Nipro Blood Collection Needle
Classification Name: Needle , Hypodermic, Single Lumen
Product Code: FMI

6. **Device Description**
Intended Use: VAKU-8™ Blood Collection Needles are designed for routine blood collection by a qualified practitoner.

Product Description: VAKU-8™ Single use Multi Sample blood collection needles are composed of a stainless steel needle tube that is ground at both ends and affixed to a plastic hub. A rubber sleeve covers the backend needle tube and hub tip. The front end needle is used to withdraw blood once placed in the patient. The needle tube is protected by a plastic needle cover on either end. The "front end needle" is designed to withdraw blood from the patient. The "back end needle" is covered by a rubber sleeve and is designed with a threaded hub that can be attached to a blood collection tube holder. The tube holder facilitates attachment to a evacuated blood collection tube. Each needle is individually packaged sterile utilizing two plastic end covers. A perforated label serves to simplify identification of needle size and also acts as a seal of integrity.

7. **Measurements**
VAKU-8™ Blood Collection Needle measurements and tolerances are as specified in British Standard 4843. They are color coded for identification according to ISO 6009.
VAKU-8™ Blood collection needles are available in six configurations.

Please find attached Annexure -1 for available meaurement and sizes

8. **SMDA Statement**
Safety and effectiveness information will be made available to interested persons upon request.

9. **Samples**
Samples of **VAKU-8™** Blood Collection Needles are included with submission.

10. **Similarities & Differences**
The following table compares the **VAKU-8™** brand Blood collection Needle to the predicate device.

K090426

BENCH MARK STUDY OF BLOOD COLLECTION NEEDLE

SL. NO.	COMPONENT	ELEMENT OF COMPARISON	PROPOSED - VAKU-8™	PREDICATE
1	NA	Intended Use	Sterile, Single Use Needle to be used for Blood Collection	Sterile, Single Use Needle to be used for Blood Collection
2	Front End Needle	Gauges	21G, 22G, 23 G	21G, 22 G
		Lengths	1" and 1.5"	1" and 1.5"
3	NA	Lumen	Single	Single
4	Unit Pack Label	Labelling	Brand Name	Brand Name
			Size	Size
			Lot No	Lot No
			Exp. Date	Exp. Date - Not mentioned on unit
			Symbol of single use	Symbol of Single use - Not mentioned on unit
			Mode of Sterilization – EtO Gas	Mode of Sterilization - EtO Gas
			Single dotted cut line on label & 1 mm gap left between the corner of label (for EO penetration)	three dotted cut line on label (for EO penetration) & label overlapped from the corner
			Only Brand Name Mentioned	Name of Manufacturer Mentioned
			Size of label - 10x27 mm	Size of label - 10x30 mm
5	Bottom Cover (Tube Side)	Total length of Device	79.20-79.30mm	75.60-75.70mm
		Maximum O.D. of Device	9.20-9.30mm	9.30-9.35mm
		Material	PP	PP
		Colour	Natural	Green
		Transparency	Transparent	Transparent
6	Top Cover (Patient Side)	Material	H.D.P.E	PP
		Colour	Off white	Natural
		Transparency	Translucent	Transparent
7	Rubber Sleeve	Colour	Gray	Gray
		Transparency	Opaque	Opaque
		Material	Latex free Isoprene	Latex free Isoprene
8	Hub	Design	Threaded	Threaded
		Colour	Green	Green
		Transparency	Transparent	Opaque

SL.NO	COMPONENT	ELEMENT OF COMPARISON	PROPOSED - VAKU-8™	PREDICATE
9	**Cannula**	Material	SUS304 Stainless Steel	SUS304 Stainless Steel
		O.D.	0.810-0.820mm	0.810-0.812mm
		Effective Length		
		-Front End Needle	25.00-25.50mm	22.60-23.00mm
		-Back End Needle	15.0-15.50mm	14.60-14.80mm
		Front End Bevel length	3.55-3.65mm	3.69-3.80mm
		Front section bevel length	1.60-1.66mm	1.55-1.60mm
		Front angle of bevel	10° 30′ – 11° 30′	9° 30′ – 10 ° 00′
10	**Performance test**	Removal of Covers	Comfortable	Comfortable
		Fitment with holder	Comfortable	Comfortable
		Maximum load	0.67-0.88N	0.83-1.00N
		Shaft friction	0.10-0.15N	0.13-1.5N
		Retraction of tube over the cannula	OK	OK
		Cannula penetration over rubber sleeve	OK	OK

11. Substantial Equivalence Determination:
Comparison Analysis

Based on the comparison, it is our conclusion that **VAKU-8™** Blood Collection needles are substantially equivalent in intended use, design, technology, materials and performance to the predicate device.

12. Conclusion:

The applicant device is **Substantially Equivalent (SE)** to the Predicate Device which is US legally marketed device. Therefore , the applicant device is determined as safe & effective.

No action is required to comply with relevant voluntary performance standards.

13. **VAKU-8™** Blood collection Needles are manufactured in compliance with BS 4843. Samples are drawn from each batch produced as per defined sampling plan, performance tests are conducted as per the standards cited above and defined criteria for acceptance are applied. Records of in-process and final performance tests for each batch are maintained by the Quality Assurance Department. A sample of the tests and validations for Blood Collection needles is enclosed in Annexure 6 and 7.

14. Biocompatibility Data

1801 (Topilene) PP used in the Hub , has been tested and it mets all requirements of a USP Class VI Plastic. Certificate of Compliance included in Annexure 2.

The materials used to produce Multi Sample Blood Collection Needle are identical to materials that are being used in the predicate device under the same conditions.

15. Sterilization

VAKU-8™ Blood collection needles are sterilized by ethylene gas at the manufacturer's in-house validation sterilization facility (as per EN 550). Validation Report is enclosed in Annexure 3. Bio-sterilization cycles are validated by using biological indicators. Samples are drawn from each sterilization load and subjected to the tests for sterility as per USP.

Manufacturer complies with SAL requirements as per guidance document. Manufacturer's sterilization cycles(exposure time, temperature and pressure) have been prepared to achieve a minimum 10^{-6} probability of survival of viable micro organisms and validated as per EN 550.
Freedom from Pyrogen is determined by taking samples from each sterilizer load and subjected to the test "freedom from Pyrogenic materials" as per USP(Annexure 10).

16. Labeling

Sample labels and packaging are displayed in Annexure 4. Samples of unit pack are enclosed. packaging is enclosed.

17. Expiration Date

The expiration date of 3 years post manufacture is derived on recommendation of the supplier of sealable medical grade tape and real time studies. The shelf life is valid for 3 years and this is also time period for which manufacturer maintains counter samples.

18. Performance and Principle of Operation

The performance and principle of Operation are identical for the **VAKU-8™** Blood collection Needle and the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Sanjiv Kumar
President and Chief Executive Officer
Myco Medical Supplies, Incorporated
158 Towerview Court
Cary, North Carolina 27513

JUN 12 2009

Re: K090426
Trade/Device Name: VAKU-8™ Blood Collection Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: May 29, 2009
Received: June 3, 2009

Dear Mr. Kumar:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/Centers_Offices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting 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):

Device Name: **VAKU-8™** Blood Collection Needle

Indications for Use: **VAKU-8™** Blood Collection Needles are designed for routine blood collection by a qualified practitioner

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)

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

510(k) Number: K090426