OCT 12 2006

Applicant's Name, Address, Telephone, Fax, Contact Person

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Contact Person

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1.0 CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

a) Classification Name: Pending - Class II
Common / Usual Name: Endoscope and accessories
Device Classification: 21 CFR § 876.1500, –Endoscope and accessories
Proprietary Name: Manzi Mach 1 Instrument Cleaner- Processor System with MS10 High Level Disinfector

b) Classification Name: Pending - Class II
Common / Usual Name: Endoscope and accessories
Device Classification: 21 CFR § 876.1500,
Proprietary Name: Manzi MS10

2.0 PREDICATE DEVICE

a) System 83 Plus™ Washer-Disinfector, K983017
Manzi Cleaner System, K043314 (Washer)
b) Steris 20 Sterilant, K875280

3.0 INDICATIONS FOR USE

The Manzi Mach 1 Instrument Cleaner Processor System is indicated for use with the High Level Disinfectant MS10 concentrate (MEC 0.49% PAA, minimum contact temperature of 120°F for a contact time of 15 minutes) for cleaning and high level disinfecting flexible bronchoscopes used in health care settings by health care workers.

4.0 DESCRIPTION OF THE DEVICE

The Manzi Mach 1 Instrument Cleaner-Processor System consists of a Manzi Mach 1 Instrument Cleaner-Processor; a proprietary Manzi germicide, MS10; and a proprietary Manzi Detergent, MD10.

The Manzi Mach 1 Instrument Cleaner-Processor is a self-contained stand-alone system of hardware and software designed to clean and provide high level disinfection of bronchoscopes using the MD10 detergent, the MS10 germicide, and a patented push-pull agitation system. The push-pull agitation system effectively scrubs the interior and exterior surfaces of the bronchoscope without the use of special connectors. The scope is placed in a processing chamber where it is exposed to a push-pull

agitation cleaning cycle followed by two hot water rinses, a push-pull agitation disinfection cycle that provides high level disinfection (spore log reduction of $\geq 10^{6}$ microorganisms with no CFUs) of the device, and a final rinse with an ozonated sanitized water rinse.

The hardware for the Manzi Mach 1 Instrument Cleaner-Processor consists of a stainless steel processing chamber, a push-pull agitation pump, an ozonator, and a variety of components that are mounted in a movable covered frame. The cleaner-processor system utilizes accessories such as disposable water filters, reusable bronchoscope trays, and printer paper.

The Manzi Mach 1 Instrument Cleaner-Processor is designed to: (1) be used in accordance with the reprocessing instructions provided in the operator's manual of the instruments being processed, and (2) facilitate the health care facility's compliance with reprocessing guidelines published by SGNA, APIC, AORN, ASGE, CDC, and other professional organizations.

MD10 is a low foaming enzyme chemical detergent packaged in single use containers for attachment to the Manzi Cleaner. MD10 is intended to be used with the Manzi Instrument Cleaner-Processor.

MS10 is a peracetic acid based liquid chemical germicide. MS10 is intended to be used with the Manzi Instrument Cleaner-Processor.

5.0 SUMMARY OF NONCLINICAL TESTS for the MANZI MACH 1 INSTRUMENT CLEANER-PROCESSOR

5.1 Qualification Testing – FDA Guidance

The Manzi Mach 1 Instrument Cleaner-Processor System was tested and found to conform with the requirements of the "**Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer / Disinfectors, and Disinfectors Intended for Use in Health Care Facilities", dated August, 1993"**. The table below identifies the qualifications performed and the results obtained:

Requirement				Results
G..	Performance Data			
	1	Process Parameter Tests		Passed
	2	Simulated Use Tests		Passed
	2.c.	Effectiveness Tests		
		2.c.(1)	Cleaning Efficacy	Passed
		2.c.(2)	Disinfection Efficacy	Passed
		2.c.(3)	Rinsing Efficacy	Passed
		2.c.(4)	Other Tests	Passed
		2.c.(5)	Combined Process	Passed
	3.	In – Use Tests		Passed
H.	Software Documentation			Passed
I.	Toxicological Evaluation of Residues			Passed

5.2 Qualification Testing – EU Guidance

The Manzi Mach 1 Instrument Cleaner-Processor System was also tested and found to conform with the requirements of the Draft prEN ISO 15883-1: 2003, Washer-disinfectors – Part 1: General Requirements, Definitions and Tests and Draft prEN ISO 15883-4: 2001, Washer-disinfectors – Part 4: Requirements and Tests for Washer-Disinfectors Employing Chemical Disinfection for Thermo-Labile Endoscopes as identified in the Table below.

prEN ISO 15883-1: 2003 Requirement		Results
6.10 Annex B Annex E	Cleaning Efficacy – Scope Ninhydrin Horse serum- prEN 15883-4 Annex B.1.1	Passed
	Cleaning Efficacy – Surrogate Ninhydrin Horse serum- prEN 15883-4 Annex B.1.1 Surrogate - prEN 15883-4	Passed
6.11 Annex D	Disinfection Efficacy – Scope Sheep blood - prEN 15883-4 Annex D	Passed
	Disinfection Efficacy – Surrogate Sheep blood - prEN 15883-4 Annex D	Passed

5.3 Qualification Testing – Langford IC Systems (LIC) Requirements

The Manzi Mach 1 Instrument Cleaner-Processor System was also tested and found to conform to the LIC requirements identified in the table below.

LIC Cleaning Requirement	Results
Cleaning Efficacy: Reduction of protein loading of scopes contaminated with a Protein Laden Soil to Remaining Protein levels of < 6.4 µg/cm² (Ref: AAMI TIR30: 2003, A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices.).	Passed Remaining Protein levels of < 4.0 µg/cm²

LIC High Level Disinfection Requirement	Results
High Level Disinfection Efficacy: Reduction of $\geq 10^6$ microbial loading of scopes with no colony forming units (CFUs)	Passed ≥ 6 spore log reduction with no CFUs

LIC Microbiological Efficacy Tests		
Test Method	Test Organisms	Results
Simulated Use Test (15 min.) ISO 15883-4 Surrogates Sheep's blood soil	Bacillus subtilis Mycobacterium terrae Candida albicans Enterococcus faecium Styphlococcus aureus	> 6 spore log reduction; no Colony Forming Units (CFU)
Simulated Use Test (15 min.) Olympus Bronchoscopes Sheep's blood soil	Bacillus subtilis	> 6 spore log reduction; no CFU
Simulated Use Test Ozonated Water System	Candida albicans, Staphylococcus aureus, Bacillus subtilis	> 6 spore log reduction; no CFU

LIC Sanitized Ozonated Water System Requirement	Results
Final Rinse System Efficacy: Reduction of $\geq 10^{6}$ microbial loading of scopes with no colony forming units (CFUs)	Passed $\geq$ 6 spore log reduction with no CFUs

6.0 SUMMARY OF NONCLINICAL TESTS for the MANZI MS10

5.1 Qualification Testing – FDA Guidance

The Manzi MS10 germicide was tested to and met the requirements of the current edition of **"Guidance for Industry and FDA Reviewers, Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants / High Level Disinfectants", dated January 3, 2000.** The table below identifies the qualifications performed and the results obtained:

Requirement		Results
5.4	Potency Test	Passed
5.5	Simulated Use Tests	Passed
5.6	In-Use Tests	Passed
6.0	Biocompatibility	Passed

Microbiological Efficacy Summary		
Test Method	Test Organisms	Results
Sporicidal Activity of Sterilants; AOAC Official Method 966.04	Bacillus subtilis Clostridium sporogenes	> 6 spore log reduction; No CFUs MS10 is sporicidal
Fungicidal Activity of Sterilants; AOAC Official Method 955.17	Trichophyton mentagrophytes	MS10 is fungicidal
Use-Dilution Method; AOAC Official Method 955.14, 955.15, 964.02	Salmonella choleraesuis Staphylococcus aureus Pseudomonas aeruginosa	MS10 is bactericidal
Virucidal Testing	Poliovirus Type 1	MS10 is virucidal
Quantitative Tuberculocidal Test	Mycobacterium bovis	MS10 is tuberculocidal

7.0 OVERALL PERFORMANCE CONCLUSIONS

The studies demonstrate that the Manzi Mach 1 Instrument Cleaner-Processor System is safe and effective for the cleaning and high level disinfection of bronchoscopes within the stated indications for use for the Manzi Mach 1 Instrument Cleaner-Processor, the Manzi MS10 germicide, and the Manzi Detergent, MD10, and establishes substantial equivalence of the Manzi Mach 1 Instrument Cleaner-Processor System to the predicate devices identified in Section 2.0 above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2006

Langford IC Systems, Incorporated
C/O Jimmie T. Johnston, Ph.D.
Vice President of Regulatory and Clinical Affairs
Proven Process Medical Devices
141 Washington Street
East Walpole, Massachusetts 02032

Re: K060458
Trade/Device Name: Manzi Mach 1 Instrument Cleaner-Processor System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FEB
Dated: September 19, 2006
Received: September 20, 2006

Dear Dr. Johnston:

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.

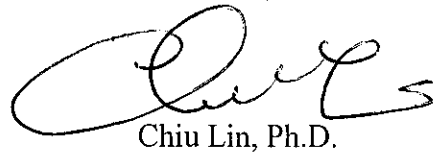
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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: K060458

Device Name: Manzi Mach 1 Instrument Cleaner - Processor System with MS10 High Level Disinfector

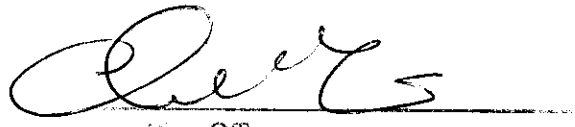
Indications for Use:

The Manzi Mach 1 Instrument Cleaner Processor System is indicated for use with the High Level Disinfectant MS10 concentrate (MEC 0.49% PAA, minimum contact temperature of 120°F for a contact time of 15 minutes) for cleaning and high level disinfecting flexible bronchoscopes used in health care settings by health care workers.

Prescription Use ___ ___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (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)



...on Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...) Number: K060458