K090414

FEB 24 2011

ATTACHMENT 2
510(k) SUMMARY

510(k) Owner:	NexEra Medical, Inc. **1556 East Commercial Blvd** Oakland Park, Fl 33334-5752
	Contact: Paul Sallarulo, President CEO Phone: 954-495-2020, x 2031 Fax: 954-491-7281
Establishment Registration Number:	TBD
Date Summary Prepared:	First submittal: February 12, 2009 Revised: August 19, 2009 Revised : December 3, 2009 Revised: January 23, 2011
Device:	Trade Name: SpectraShield model 9500 Surgical Respirator Common /Classification Name: Surgical Respirator Classification Product Code: ONT Regulation Number: 21CFR 878.4040 Regulation Class: II
Predicate Device Information:	K061716 Prestige Ameritech Surgical Mask Prestige Ameritech Earloop Surgical Mask-Blue, Pink, Green,White,Yellow, Peach Prestige Ameritech Earloop Surgical Mask with splash shield-Blue Green, White, Peach Prestige Ameritech Earloop Surgical Mask Tissue-Blue, Pink, White, Yellow Prestige Ameritech Tie on Surgical Mask-Blue, Pink, Green, White, Peach Prestige Ameritech Tie on Surgical Mask with splash shield-Blue, Green, White, Peach
Device Description:	The SpectraShield model 9500 Surgical Respirator is a molded shape surgical respirator composed of 4 layers of material, molded to form the respirator. A 2-ply meltblown polypropylene middle layer is sandwiched by inner and outer layers of 100% polyester nonwoven fabric. The inner and outside layers of polyester nonwoven fabric include fibers that have been embedded with an antimicrobial agent to provide antimicrobial performance. The respirator has 2 latex-free non-allergenic elastic straps and an aluminum nose strip.
Intended Use:	The SpectraShield 9500 Surgical N95 Respirator is a single use, disposable, surgical N95 respirator, embedded with a zeolite carrier containing a silver-copper agent on the outer layer and is not an antimicrobial drug. SpectraShield 9500 kills 99.99% of test bacteria after one hour of contact with the surface of the respirator. In vitro (laboratory) tests have demonstrated 99.99% kill on the surface of the outer layer of the respirator when tested in vitro against single isolates of the following test bacteria: Streptococcus pyogenes, MRSA (Methicillin Resistant Staphylococcus

aureus), and Haemophilus influenzae, under tested contact conditions.

No clinical studies have been conducted comparing the ability of an untreated surgical N95 respirator and the SpectraShield model 9500 surgical N95 respirator to protect the wearer from infection, and the antibacterial treatment cannot effect pathogens that are inhaled around the edges of the respirator.

The SpectraShield 9500 Surgical N95 respirator is a single use device, intended for occupational use to protect against microorganisms, body fluids, and particulate material

510(k) Summary
Device Comparison Table

	New Device	**Predicate Device**
510(k) #	To be determined	K061716
Company	NexEra Medical, Inc.	Prestige Ameritech
Name/Model	**SpectraShield model 9500 Surgical Respirator**	**Prestige Ameritech Surgical Mask**
Fabrics:	Nonwoven polyester containing silver-copper zeolite and a meltblown polypropylene substrate.	Cellulose, spun bonded polypropylene, and medical grade tissue
Nosepiece:	100% Aluminum	Malleable Aluminum nosepiece strip
Straps	(2) Polyamide fiber and elastic straps, and does not contain natural rubber latex.	Tie strips or latex free elastic loops
Mask Style:	Molded shape	Flat folded , pleated
Fluid Resistance: **ASTM F1862**	Pass: Fluid Resistant @ 160mm Hg	Pass: Fluid Resistant
Particulate Filtration Efficiency: **ASTM F2299**	Pass: 99.87% at 0.1 microns	Pass: 98.5% at 0.1 microns
Differential Pressure: **Mil M36954C**	Pass: 4.3mm H_2O/cm^2	Pass: 2.6 mm H_2O/cm^2
Bacterial Filtration Efficiency: **ASTM F2101**	Pass: 99.9%	Pass: 99.6%

Flammability Class: **16CFR 1610**	Class 1	Class1
Cytotoxicity: **10993-10**	USP reactivity score = < 2, Pass	Not Available
Primary skin irritation: **ISO10993-10**	PSI Score = 0, Non-irritant, Pass	Not Available
Repeated Patch Dermal Sensitization **ISO 10993-10**	0% incidence sensitization response "0" severity at each evaluated time point. Pass	Not Available
Systemic Toxicity **ISO 10993-11**	No mortality or evidence of systemic toxicity from the extracts was observed. Pass	Not Available
Physico-chemical **USP Physico-chemical Test-Plastics**	Test results met the USP limits. Pass	Not Available
Gas off Testing	Total antimicrobial particles released from the device were verified to be within safe inhalation levels.	Not Available
Leach off testing	Total leachable antimicrobial particles released from the device were verified to be within safe orally ingestible levels.	Not Available

Conclusion: It is our conclusion that the SpectraShield model 9500 Surgical Respirator meets the requirements for the tests recommended for evaluation and risk analysis outlined in the (1) Guidance Document for Surgical Masks and the (2) Guidance Document for Medical Devices that Include Antimicrobial Agents. The testing included in this submission demonstrates that the technological characteristics of the SpectraShield model 9500 Surgical Respirator, with the specified antimicrobial agent, does not raise any question of safety and effectiveness,

The SpectraShield model 9500 Surgical Respirator is substantially equivalent in safety and effectiveness to the Prestige Ameritech Surgical Mask (predicate device) named in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Paul Sallarulo
President CEO
NexEra Medical, Incorporated
1556 East Commercial Boulevard
Oakland Park, Florida 33334-5752

FEB 24 2011

Re: K090414
Trade/Device Name: SpectraShield model 9500 Surgical Respirator
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Respirator
Regulatory Class: II
Product Code: ONT
Dated: January 24, 2011
Received: January 26, 2011

Dear Mr. Sallarulo:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

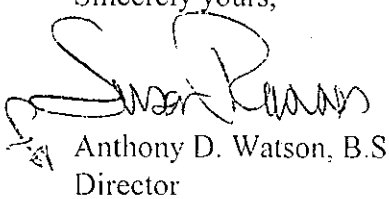
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/CentersOffices/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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., MS. M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 1

Indications for Use

510(k) Number: K090414

Device Name: SpectraShield model 9500 Surgical Respirator

Indications for Use:

The SpectraShield 9500 Surgical N95 Respirator is a single use, disposable, surgical N95 respirator, embedded with a zeolite carrier containing a silver-copper agent on the outer layer and is not an antimicrobial drug. SpectraShield 9500 kills 99.99% of test bacteria after one hour of contact with the surface of the respirator. In vitro (laboratory) tests have demonstrated 99.99% kill on the surface of the outer layer of the respirator when tested in vitro against single isolates of the following test bacteria: Streptococcus pyogenes, MRSA (Methicillin Resistant Staphylococcus aureus), and Haemophilus influenzae, under tested contact conditions.

No clinical studies have been conducted comparing the ability of an untreated surgical N95 respirator and the SpectraShield model 9500 surgical N95 respirator to protect the wearer from infection, and the antibacterial treatment cannot effect pathogens that are inhaled around the edges of the respirator.

The SpectraShield 9500 Surgical N95 respirator is a single use device, intended for occupational use to protect against microorganisms, body fluids, and particulate material.

Prescription Use _____ AND/OR Over –the-counter Use _ X _
(21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – ONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Confidential

Elizabeth F. Claverie-Wilson 01/23/11

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

510(k) Number: K090414