DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 29, 2015

Nexera Medical Inc.
Mr. Paul Sallarulo, President & CEO
3343 West Commercial Blvd, Suite 103
Ft. Lauderdale, FL 33309

Re: K150729
Trade/Device Name: SpectraShield Model 9500 Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Mask
Regulatory Class: II
Product Code: ONT
Dated: November 30, 2015
Received: December 1, 2015

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 contact 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. 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,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150729

Device Name
SpectraShield model 9500 Surgical Mask

Indications for Use *(Describe)*

The SpectraShield 9500 Surgical Mask is a single use, disposable, surgical mask, tested for continuous use up to 8 hours, 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, and inactivates 99.99% of test influenza viruses after 5 minutes of contact with the surface of the mask. 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.

In vitro tests have demonstrated 99.99% inactivation on the surface of the outer layer of the mask when tested against the following seasonal, pandemic, avian, swine and equine influenza viruses: Influenza A subtypes: H1N1 (A/California/04/2009, A/Brisbane/59/2007, A/Wisconsin/10/1998, A /Puerto Rico/8/1934), H3N2 (A/Wisconsin/67/2005, A/Brisbane/10/2007, A/Hong Kong/8/1968, A/Victoria/3/75), H2N2 (A/2/Japan/305/1957); Avian Flu (bird flu) subtypes: Avian Influenza A (H5N1), Avian Influenza A (H9N2), Swine Flu subtype: H1N1 (A/Swine/1976/1931), Equine Flu subtypes: H3N8 (A/Equine/2/Miami/1963), Influenza B strains: B/Florida/4/2006, B/Brisbane/60/2008, B/Lee/40.

No clinical studies have been conducted comparing the ability of an untreated surgical mask and the SpectraShield model 9500 surgical mask to protect the wearer from infection, and the antibacterial/anti-influenza virus treatment cannot affect pathogens that are inhaled around the edges of the respirator.

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

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5.0: 510(k) SUMMARY (K150729)

510(k) Owner:	NexEra Medical, Inc. 3343 West Commercial Blvd, Suite 103 Ft. Lauderdale, FL 33309	
	Contact: Phone: Fax:	Paul Sallarulo, President CEO 954-495-2020, x 2031 954-491-7281
Date Summary Prepared:	December 29, 2015	
Device:	Trade Name: Common /Classification Name: Class: Classification Product Code: Regulation Number:	SpectraShield model 9500 Surgical Mask Surgical mask II ONT 21 CFR 878.4040
Predicate Device Information:	K120244 SpectraShield 9500 Surgical N95 Respirator K122702 BioFriend™ BioMask ™ N95 Surgical Respirator	
Device Description:	The SpectraShield model 9500 Surgical Mask is a molded shape surgical mask composed of 4 layers of material, molded to form the mask. 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 antibacterial/antiviral agent to provide antibacterial and antiviral performance. The mask has 2 elastic straps (not made with natural latex) and an aluminum nose strip.	
Intended Use:	The SpectraShield 9500 Surgical Mask is a single use, disposable, surgical mask, tested for continuous use up to 8 hours, 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, and	

inactivates 99.99% of test influenza viruses after 5 minutes of contact with the surface of the mask. *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.

In vitro tests have demonstrated 99.99% inactivation on the surface of the outer layer of the mask when tested against the following seasonal, pandemic, avian, swine and equine influenza viruses: Influenza A subtypes: H1N1 (A/California/04/2009, A/Brisbane/59/2007, A/Wisconsin/10/1998, A /Puerto Rico/8/1934), H3N2 (A/Wisconsin/67/2005, A/Brisbane/10/2007, A/Hong Kong/8/1968, A/Victoria/3/75), H2N2 (A/2/Japan/305/1957); Avian Flu (bird flu) subtypes: Avian Influenza A (H5N1), Avian Influenza A (H9N2), Swine Flu subtype: H1N1 (A/Swine/1976/1931), Equine Flu subtypes: H3N8 (A/Equine/2/Miami/1963), Influenza B strains: B/Florida/4/2006, B/Brisbane/60/2008, B/Lee/40.

No clinical studies have been conducted comparing the ability of an untreated surgical mask and the SpectraShield model 9500 surgical mask to protect the wearer from infection, and the antibacterial/anti-influenza virus treatment cannot affect pathogens that are inhaled around the edges of the respirator.

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

510(k) Summary
Device Comparison Table

3343 West Commercial Blvd., Suite 103 – Ft. Lauderdale, FL 33309 USA
Telephone: 954-495-2020 ~ Fax: 954-495-7281 ~ www.nexeramed.com

	Subject Device	Predicate Device K120244 SpectraShield	Predicate Device K122702 BioFriend™ BioMask ™
510(k) #	K150729	K120244	K122702
Company	NexEra Medical, Inc.	NexEra Medical, Inc.	Filligent (HK) Limited
Name/Model	**SpectraShield Model 9500 Surgical Mask *** (*with amended Intended use Statement)	**SpectraShield Model 9500 Surgical Respirator**	BioFriend™ BioMask ™ N95 Surgical Respirator: Professional BF-200-3013AN
Fabrics	Nonwoven polyester containing a silver-copper zeolite (antibacterial / aniviral agent) and a meltblown polypropylene substrate.	Nonwoven polyester containing a silver-copper zeolite (antibacterial agent) and a meltblown polypropylene substrate.	4 layers: spun-bond polypropylene, cellulose / polyester, meltblown polypropylene, spunbond polypropylene. Copper & zinc ion treatment and a hydrophilic plastic coating.
Nosepiece	100% Aluminum	100% Aluminum	100% Aluminum
Straps	(2) Polyamide fiber and elastic straps, not made with natural latex	(2) Polyamide fiber and elastic straps, latex free	Polyamide/spandex elastic straps, latex free
Mask Style	Molded shape	Molded shape	Convex shape
Fluid Resistance ASTM F1862	Pass: Fluid Resistant @ 160mm Hg	Pass: Fluid Resistant @ 160mm Hg	160 mm Hg
Particulate Filtration Efficiency ASTM F2299	Pass: 99.87% at 0.1 microns	Pass: 99.87% at 0.1 microns	>99.9%
Differential Pressure Mil M36954C	Pass: 4.3mm H_20/cm^2	Pass: 4.3mm H_20/cm^2	4.9mm H_20/cm^2
Bacterial Filtration Efficiency ASTM F2101	Pass: 99.9%	Pass: 99.9%	>99.9%

	Subject Device	Predicate Device K120244 SpectraShield	Predicate Device K122702 BioFriend™ BioMask ™
Flammability Class 16CFR 1610	Class 1	Class 1	Class 1
Cytotoxicity 10993-10	Pass: USP reactivity score = < 2	Pass: USP reactivity score = < 2	PASS
Primary skin irritation ISO10993-10	Pass: PSI Score = 0, Non-irritant	Pass: PSI Score = 0, Non-irritant	PASS
Repeated Patch Dermal Sensitization ISO 10993-10	Pass: 0% incidence sensitization response "0" severity at each evaluated time point.	Pass: 0% incidence sensitization response "0" severity at each evaluated time point.	PASS
Systemic Toxicity ISO 10993-11	Pass: No mortality or evidence of systemic toxicity from the extracts was observed.	Pass: No mortality or evidence of systemic toxicity from the extracts was observed.	PASS
Physico-chemical USP Physico-chemical Test-Plastics	Pass: Test results met the USP limits.	Pass: Test results met the USP limits.	PASS
Gas off Testing	Total antibacterial / antiviral particles released from the device were verified to be within safe inhalation levels.	Total antibacterial particles released from the device were verified to be within safe inhalation levels.	PASS
Leach off testing	Total leachable antibacterial / antiviral particles released from the device were verified to be within safe orally ingestible levels.	Total leachable antibacterial particles released from the device were verified to be within safe orally ingestible levels.	PASS
Bacterial Reduction:	T_0 Inoculums measured $>10^6$ Bacterial contact @ 1 hour *S.pyogenes*: >4.40$\log_{10}$ reduction *H.influenzae*:>6.20$\log_{10}$	T_0 Inoculums measured, $>10^6$ Bacterial contact @ 1 hour *S.pyogenes*: >4.40$\log_{10}$ reduction *H.influenzae*:>6.20$\log_{10}$	NA

	Subject Device	Predicate Device K120244 SpectraShield	Predicate Device K122702 BioFriend™ BioMask ™
	reduction MRSA:> 4.83$\log_{10}$	reduction MRSA:> 4.83$\log_{10}$	
Bacterial Reduction: after repeated exposures to perspiration over 12 hours	T_0 Inoculums measured >10^6 Bacterial contact = 1 hour *S.pyogenes*: > 4.25$\log_{10}$ reduction *H.influenzae*: >4.18$\log_{10}$reduction MRSA: > 4.11$\log_{10}$reduction	T_0 Inoculums measured, >10^6 Bacterial contact = 1 hour *S.pyogenes*: > 4.25$\log_{10}$ reduction *H.influenzae*: >4.18$\log_{10}$reduction MRSA: > 4.11$\log_{10}$reduction	NA
Viral Reduction:	99.99 % (>4.0 $\log_{10}$) reduction of **16** different strains of Influenza A & Influenza B viruses after 5 minutes contact with the surface of the mask.	NA	99.99 % (>4.0 $\log_{10}$) reduction of **15** different strains of Influenza A & Influenza B viruses after 5 minutes contact with the surface of the mask.
Repeat Virus Challenge After Extended Wear by Human Subjects:	99.99 % (>4.0 $\log_{10}$) reduction of 2 virus, Influenza A (H1N1) & Avian Influenza virus (H5N1) viruses after 5 minutes contact with the surface of the masks that had been worn for 4 hours and 8 hours .	NA	NA
Intended Use Statement:	The SpectraShield 9500 Surgical Mask is a single use, disposable, surgical mask, tested for continuous use up to 8 hours, 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, and inactivates 99.99% of test influenza viruses after 5 minutes of contact with the surface of the mask. *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	The SpectraShield 9500 Surgical N95 Respirator is a single use, disposable, surgical N95 respirator, tested for continuous use up to 8 hours, 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	The BioFriend™ BioMask™ N95 surgical respirator is a single use NIOSH-approved, disposable N95 surgical respirator with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2% w/w, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% w/w and zinc 1.6% w/w which form ionic bonds with negatively charged side groups on the influenza viruses). The BioFriend™ BioMask™ N95 surgical respirator inactivates 99.99% of tested influenza viruses on five minutes contact with the surface of the respirator in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine, and equine influenza viruses: Influenza A subtypes and strains H1N1 (the 2009

	Subject Device	Predicate Device K120244 SpectraShield	Predicate Device K122702 BioFriend™ BioMask ™
	contact conditions. *In vitro* tests have demonstrated 99.99% inactivation on the surface of the outer layer of the mask when tested against the following seasonal, pandemic, avian, swine and equine influenza viruses: Influenza A subtypes: H1N1 (A/California/04/2009, A/Brisbane/59/2007, A/Wisconsin/10/1998, A /Puerto Rico/8/1934), H3N2 (A/Wisconsin/67/2005, A/Brisbane/10/2007, A/Hong Kong/8/1968, A/Victoria/3/75), H2N2 (A/2/Japan/305/1957); Avian Flu (bird flu) subtypes: Avian Influenza A (H5N1), Avian Influenza A (H9N2), Swine Flu subtype: H1N1 (A/Swine/1976/1931), Equine Flu subtypes: H3N8 (A/Equine/2/Miami/1963), Influenza B strains: B/Florida/4/2006, B/Brisbane/60/2008, B/Lee/40. No clinical studies have been conducted comparing the ability of an untreated surgical mask and the SpectraShield model 9500 surgical mask to protect the wearer from infection, and the antibacterial/anti-influenza virus treatment cannot affect pathogens that are inhaled around the edges of the respirator. The SpectraShield 9500 Surgical Mask is a single use device, intended for occupational use to protect against microorganisms, body fluids, and particulate material. .	*Staphylococcus aureus)*, and Haemophilus influenzae under tested contact conditions. No clinical studies have been conducted comparing the ability of the 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.	pandemic flu subtype A/California/04/2009, A/Brisbane/59/2007, A/Wisconsin/10/1998, A/New Jersey/8/1976, A/Puerto Rico/8/1934), H3N2(A/Brisbane/10/2007, A/Wisconsin/67/2005), H2N2 (A/2/Japan/305/1957); the bird flu subtypes: H5N1 (NIBRG-14), N9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/1931); the equine flu subtype: H3N8 (A/Equine/2/Miami/1963); and Influenza B strains: (B/Florida/4/2006, B/Lee/1940), under tested contact conditions. Correlation between in vitro testing results and any clinical event has not been tested. The BioFriend™ BioMask™ N95 surgical respirator, Model: Professional (BF-200-3013AN) is flat folded and expands into a convex-shaped mask with polyamide/spandex elastic head-loops to secure the mask to the user's face, and a malleable aluminum strip positioned above the nose for a tighter seal around the nose and face. The device is intended to be worn during seasonal influenza A or Influenza B, and an Influenza A or Influenza B pandemic. It is intended for occupational use, to help reduce wearer exposure to pathogenic biological airborne particulates, and to protect against the transfer of micro-organisms, body fluids, and particulate material.

Conclusion: Based on the intended use, technological characteristics, performance data, clinical and nonclinical tests performed, the subject SpectraShield Model 9500 Surgical Mask is substantially equivalent and is as safe and as effective as the legally marketed predicate device.