regenlab

K122122 page 1 of 2

510(k) SUMMARY
Regen Spray Applicator (models R-A/NAC1 & R-A/NAC3)

NOV 9 2012

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

RegenLab America
3428 Avenue Marcil
Montreal (Quebec) H4A 2Z3
Canada

Phone: (514) 817-6704
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Contact Person: Guy Fortier, Ph.D.

Date Prepared: 4th July, 2012

Name of Device and Name/Address of Sponsor

Name of Device: Regen Spray Applicator (models R-A/NAC1 & R-A/NAC3)

Sponsor: Regen Lab SA
En Budron B2
Le Mont-sur-Lausanne,
Vaud, CH-1052
Switzerland

Classification Name	Piston, Syringe (21 CFR 880.5860)
Classification	Class II
Product Code	FMF
Predicate Devices	Fibrijet Aerosol Applicator (K012868) from Micromedics;

Intended Use / Indications for Use
The Regen Spray Applicator (models R-A/NAC1 & R-A/NAC3) is designed for use in applying two non-homogeneous fluids or liquids to a treatment site as deemed necessary by the clinical use requirements.

Regen Spray Applicator (models R-A/NAC1 & R-A/NAC3) is for single use only.

Technological Characteristics

The Regen Spray Applicator (models R-A/NAC1 & R-A/NAC3) is a self-contained disposable kit aiding to simultaneous delivery of two non-homogeneous fluids or liquids to a treatment site-as deemed necessary by the clinical use requirements.

The Regen Spray Applicator (models R-A/NAC1 & R-A/NAC3) is comprised of sterile disposable needles, syringe holder, double piston stopper, nozzle, and syringes.

Sterilization

The Regen Spray Applicator (models R-A/NAC1 & R-A/NAC3) is terminally sterilized by gamma irradiation (minimal dose: 25 kGy). Full cycle sterilization is designed to provide a minimum Sterility Assurance Level (SAL) of 10^{-6}.

Safety and Performance Data

Biocompatibility data have been provided to support the safety of Regen Spray Applicator (models R-A/NAC1 & R-A/NAC3). No performance standards have been developed for this type of device.

In all instances, the Regen Spray Applicator (models R-A/NAC1 & R-A/NAC3) functioned as intended and the performance based on fluids dispensed from the applicator when the syringe plungers are depressing was as expected.

Substantial Equivalence

The Regen Spray Applicator (models R-A/NAC1 & R-A/NAC3) is as safe and effective as the predicate device. The Regen Spray Applicator (models R-A/NAC1 & R-A/NAC3) has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between Regen Spray Applicator (models R-A/NAC1 & R-A/NAC3) and its predicate device raise no new issues of safety or effectiveness. Thus, Regen Spray Applicator (models R-A/NAC1 & R-A/NAC3) is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 9, 2012

Regen Lab SA
C/O Guy Fortier, Ph.D.
RegenLab America
3428 Avenue Marcil
Montreal, Quebec H4A 2Z3
CANADA

Re: K122122
Trade/Device Name: Regen Spray Applicator (models R-A/NAC1 and R-A/NAC3)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: July 4, 2012
Received: July 7, 2012

Dear Dr. Fortier:

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,

DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anthony D. Watson, 0.9.2342.19200300.100.1.1=1300092402
Date: 2012.11.09 13:59:57 -05'00'

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

Enclosure

Indications for Use Statement

510(k) Number (if known):_____

Device Name: Regen Spray Applicator (models R-A/NAC1 & R-A/NAC3)

Indications for Use:

Regen Spray Applicator (models R-A/NAC1 & R-A/NAC3) is designed for use in applying two non-homogeneous fluids or liquids to a treatment site as deemed necessary by the clinical use requirements.

Regen Spray Applicator (models R-A/NAC1 & R-A/NAC3) is for single use only.

Prescription Use _____X_____ AND/OR Over-The-Counter Use _____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for RZC Nov 9, 2012

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

510(k) Number: K122122