APR 14 2014

510(K) SUMMARY FOR THE NAMIC RCS

Date prepared: January 24, 2014

A. Sponsor

Navilyst Medical, Inc
26 Forest Street
Marlborough, MA 01752

B. Contact

Brandon M. Brackett
Specialist, Global Regulatory Affairs
508-658-7984

OR

Wanda Carpinella
Director of Global Regulatory Affairs
508-658-7929

C. Device Name

Trade Name	NAMIC RCS
Common/Usual name:	Piston Syringe
Classification Name:	Syringe, Piston (21CFR§880.5860, Class II)
Classification Panel:	General Hospital

D. Predicate Device(s)

Common/Usual name:	Piston Syringe
Classification Name	Syringe, Piston - 21CFR§880.5860, Class II
Classification Panel:	General Hospital
Premarket Notification	K113198, K875196, K873955

E. Device Description

Intended Use

The NAMIC RCS is intended to be used for the intra-arterial or intra-venous administration of radiographic contrast media and saline solutions during an angiographic procedure.

F. Summary of Similarities and Differences in Technological Characteristics and Performance

The proposed NAMIC RCS syringes incorporate similar materials, design, components, technological characteristics, and intended us as the predicate syringes.

G. Performance Data

The NAMIC RCS is substantially equivalent to the predicate devices based on comparison of technological characteristics and the results of non-clinical tests which included the performance evaluation conducted in accordance with the following FDA guidance documents, international standards, and testing which included:

- FDA's *"Guidance on the Content of Premarket Notification 510(k) Submissions for Piston Syringes dated April 1993"*
- ISO 7886-1:1997 *"Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use"*
- ISO 594-2:1998 "*Conical Fittings 6% (Luer) Taper for Syringes, Needles, Certain Other Medical Equipment – Part 2: Lock Fittings*"

H. Conclusion

The results of the non-clinical testing and a comparison of similarities and differences demonstrate that the proposed and predicate devices are 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 20993-0002

April 14, 2014

Navilyst Medical, Inc.
Brandon M. Brackett
Global Regulatory Affairs Specialist
26 Forest Street
Marlborough, MA 01752

Re: K140194
Trade/Device Name: NAMIC RCS
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: January 24, 2014
Received: January 27, 2014

Dear Mr. Brackett:

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.
Acting 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)*
K140194

Device Name
NAMIC RCS

Indications for Use *(Describe)*
The NAMIC RCS is intended to be used for the intra-arterial or intra-venous administration of radiographic contrast media and saline solutions during an angiographic procedure.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2014.04.14 08:59:45 -04'00'

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