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

March 2, 2017

Solace Therapeutics, Inc.
William Gruber
President and CEO
135 Newbury Street
Framingham, MA 01701

Re: K162356
Trade/Device Name: Vesair Cystoscopic Sheath
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: KNY
Dated: February 7, 2017
Received: February 8, 2017

Dear William Gruber:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K162356

Device Name
Vesair Cystoscopic Sheath

Indications for Use *(Describe)*
The Vesair Cystoscopic Sheath is intended to facilitate the introduction of catheters or instruments into the urethra. The Vesair Cystoscopic Sheath is indicated for use as a guide for urological catheters or instruments inserted into the urethra and as a lubricious barrier between the urethral tissue and the catheter or instrument.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR 807.92 and the requirements of the Safe Medical Device ACT (SMDA) of 1990.

1. Sponsor Name

Submitter's Name:	Solace Therapeutics
Address:	135 Newbury St, Framingham, MA 01701
Phone:	(508) 283-1200
Fax:	(508) 283-1199
Contact Person:	William Gruber
Date of Preparation:	August 22, 2016

2. Device Information

Trade Name:	Vesair Cystoscopic Sheath
Common Name:	Urological catheter
Class:	II
Classification Name:	Urological catheter (21 CFR 876.5130, Product Code KNY)

3. Predicate Devices

Guardian Urethral Sheath (K141252)

4. Device Description

The Vesair Cystoscopic Sheath is intended for use in visualizing the urethra and bladder as well as the establishment of a protective tract into the bladder to facilitate atraumatic insertion of catheters and instruments through the urethra.

The Vesair Cystoscopic Sheath Assembly includes a Visual Obturator, Sheath and the Vesair Single-Use Sterile Seal. The Sheath is provided non-sterile and requires cleaning and steam sterilization prior to use.

5. Intended Use

The Vesair Cystoscopic Sheath is intended to facilitate the introduction of catheters or instruments into the urethra. The Vesair Cystoscopic Sheath is indicated for use as a guide for urological catheters or instruments inserted into the urethra and as a lubricious barrier between the urethral tissue and the catheter or instrument.

6. Comparison of Technological Characteristics

The Vesair Cystoscopic Sheath is substantially equivalent in Guardian Urethral Sheath K141252. Improvements from the Guardian Urethral Sheath include modifications to the length, material, ID/OD, sterilization methodology, Obturator change, and Seal Assembly change.

Feature/Specification	Guardian Urethral Sheath (K141252)	Vesair Cystoscopic Sheath
Working Length	55 mm	166 mm
Material	Polymer	Stainless Steel
Sterilization	Ethylene Oxide	Steam
Inner Diameter	20 Fr	19.5 Fr
Outer Diameter	21 Fr	22.5 Fr
Obturator Change	Blunt nose – no cystoscope compatibility	Blunt nose with cystoscope compatibility
Seal Assembly	No assembly required	Seal to be replaced between uses by user

Table 1 – Comparison of Proposed Vesair Cystoscopic Sheath to predicate Guardian Urethral Sheath

7. Performance Data

In Vitro Performance Testing
In vitro performance tests were performed on the Vesair Cystoscopic Sheath. The following were performed**:**

- Design Verification Testing / Simulated Use Testing
- Ship Testing
- Repeat Steam Sterilization Testing
- Accelerated Aging

8. Conclusion

Based upon the *in vitro* performance tests, the Vesair Cystoscopic Sheath has been shown to be substantially equivalent to the currently marketed Guardian Urethral Sheath K141252.