December 19, 2017

Solace Therapeutics, Inc.
Scott Blood
Vice President, Quality Assurance and Regulatory Affairs
135 Newbury Street
Framingham, MA 01701

Re: K170862
Trade/Device Name: Vesair 0 degree Cystoscope, Vesair 30 degree Long Cystoscope, Vesair 70 degree Long Cystoscope,Vesair 30 degree Cystoscope,Vesair 70 degree Cystoscope
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ
Dated: November 3, 2017
Received: November 6, 2017

Dear Scott Blood:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170862

Device Name
Vesair 0 degree Cystoscope, Vesair 30 degree Long Cystoscope, Vesair 70 degree Long Cystoscope,Vesair 30 degree Cystoscope,Vesair 70 degree Cystoscope

Indications for Use *(Describe)*
Vesair Cystoscopes are indicated to provide the user with the means for endoscopic diagnostic and therapeutic surgical procedures. Examples for the use of the devices include the visualization and manipulation of anatomy as the surgeon deems appropriate. Vesair Cystoscopes are intended to be used in general urological surgery through a minimally invasive approach by utilizing natural orifices to access the surgical site.

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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510(k) Summary

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:	Scott Blood, Vice President Quality Assurance & Regulatory Affairs
Date of Preparation:	December 18, 2017

2. Device Information

Trade Name:	Vesair 0 degree Cystoscope, Vesair 30 degree Long Cystoscope, Vesair 70 degree Long Cystoscope, Vesair 30 degree Cystoscope, Vesair 70 degree Cystoscope
Common Name:	Cystoscope
Regulation Number:	21 CFR 876.1500
Regulation Name:	Endoscope and Accessories
Class:	II
Product Code:	FAJ

3. Predicate Device

Schoelly Cystoscopes K150158

4. Device Description

The Vesair Cystoscopes described in this submission are rigid reusable endoscopes for visualization of the operating site during cystoscopic minimally invasive procedures in conjunction with a commercially available light guide, light source, video camera, monitor, and printer. Light that is created by an external light source is transmitted from the endoscope's light guide connector through the endoscope itself to the tip via a fiber optic system. Images are transferred the other way back through a rigid lens system.

Technical parameters of the Vesair Cystoscopes that characterize the optical view are the Direction of View (0°, 30°, 70°) and the Field of View (105°). The image can be displayed by a camera/monitor system which can be connected to the endoscope eyepiece. The Vesair Cystoscopes have the same diameter (4mm), and are available in different lengths of the insertion tube (0° - 280mm length, 30°- 185mm or 278mm length, 70° - 185mm or 281mm length). None of the cystoscope models have a working channel. Like other currently marketed rigid cystoscopes, all models have patient-contacting outer surfaces mainly made from metal (304 stainless steel) and incorporate fiber optics for light transmission and rigid lenses for image transmission.

Each cystoscope model is provided non-sterile and requires cleaning and steam sterilization prior to use and between subsequent uses.

5. Intended Use

Vesair Cystoscopes are indicated to provide the user with the means for endoscopic diagnostic and therapeutic surgical procedures. Examples for the use of the devices include the visualization and manipulation of anatomy as the surgeon deems appropriate. Vesair Cystoscopes are intended to be used in general urological surgery through a minimally invasive approach by utilizing natural orifices to access the surgical site.

6. Comparison of Technological Characteristics

The Vesair Cystoscopic Sheath is substantially equivalent to the Schoelly Cystoscope per **Table 1**:

Table 1 - Comparison of Proposed Vesair Cystoscope to Predicate Device

Feature/Specification	**Proposed Vesair Cystoscope**	**Schoelly Cystoscope K150158**
Patient-Contacting Material	Stainless Steel	Stainless Steel
Sterilization	Steam	Steam
Outer Diameter	4mm	Available in 2.9mm and 4mm sizes
Working length	0° - 280mm 30° -185mm or 278mm 70° -185mm or 281mm	Available in 280mm, 298mm, 300mm, 302mm,303mm
Working Channel	Not available	Not available
Direction of View	Available in 0°,30°,70°	Available in 0°,5°,12°,25°,30°,70°
Field of View	105°	70° - 85°
Indications for Use	Vesair Cystoscopes are indicated to provide the user with the means for endoscopic diagnostic and therapeutic surgical procedures. Examples for the use of the devices include the visualization and manipulation of anatomy as the surgeon deems appropriate. Vesair Cystoscopes are intended to be used in general urological surgery through a minimally invasive approach by utilizing natural orifices to access the surgical site.	The Schoelly Cystoscopes/Hysteroscopes and Accessories arc indicated to provide the user with the means for endoscopic diagnostic and therapeutic surgical procedures. Examples for the use of the devices include the visualization and manipulation of anatomy as the surgeon deems appropriate. The Schoelly Cystoscopes/Hysteroscopes and Accessories are intended to be used in general urological and gynecological surgery through a minimally invasive approach by utilizing natural orifices to

Feature/Specification	Proposed Vesair Cystoscope	Schoelly Cystoscope K150158
		access the surgical site.

7. Reference Device

These same models have already been cleared for marketing by FDA (K080560) for use in arthroscopic procedures. The proposed Vesair Cystoscope is the exact same device as the Henke Sass Wolf Arthroscope, except for the working length and Indications for Use.

Table 2 - Comparison of Proposed Vesair Cystoscope to Reference Device

Feature/Specification	Proposed Vesair Cystoscope	Henke Sass Wolf Arthroscope K080560
Patient-Contacting Material	Stainless Steel	Stainless Steel
Sterilization	Steam	Steam
Outer Diameter	4mm	4mm
Working length	0° - 280mm 30° -185mm or 278mm 70° -185mm or 281mm	185mm
Working Channel	Not available	Not available
Direction of View	Available in 0°,30°,70°	Available in 0°,30°,70°
Field of View	105°	105°
Indications for Use	Vesair Cystoscopes are indicated to provide the user with the means for endoscopic diagnostic and therapeutic surgical procedures. Examples for the use of the devices include the visualization and manipulation of anatomy as the surgeon deems appropriate. Vesair Cystoscopes are intended to be used in general urological surgery through a minimally invasive approach by utilizing natural orifices to access the surgical site.	The HSW Arthroscope and accessories is a tubular endoscopic device with accessory devices which attach to the Arthroscope and is intended to examine and / or perform surgery on the interior of a joint. Arthroscopic minimal invasive procedures are performed in the hip, knee, shoulder, wrist (carpal tunnel syndrome), temporal-mandibular joint, ankle, elbow and feet (plantar fascia release).

8. Performance Testing

Performance tests on the bench were performed on the Vesair Cystoscope. The following were performed**:**

- Reprocessing validation study
- Biocompatibility Testing
- Electrical and Thermal Safety Testing

- Shelf-life study
- Optical image quality testing

All bench testing has been performed and all components, subassemblies and/or full devices and systems have met the required specifications for the completed tests.

9. Summary

Solace Therapeutics, Inc. has demonstrated that the Vesair Cystoscope is substantially equivalent to its listed predicate devices.