DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 3, 2017

CuraSeal, Inc.
% Mr. Kit Cariquitan
Experien Group, LLC
755 North Mathilda Ave
Sunnyvale, CA 94085

Re: K162388
Trade/Device Name: CuraSeal PICS Fistulae Closure Device -PICS - AF - M1™ PICS - AF - M2™
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM
Dated: December 16, 2016
Received: December 19, 2016

Dear Mr. Cariquitan:

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,

Binita S. Ashar -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K162388

Device Name
CuraSeal Percutaneous Intraluminal Closure System for Anorectal Fistulas (PICS-AF™)

Indications for Use *(Describe)*
The CuraSeal Percutaneous Intraluminal Closure System for Anorectal Fistulas (PICS-AF™) is for implantation to reinforce soft tissue for the repair of anal and rectal fistulas.

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)*

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510(k) Notification K_____K162388, pg. 1 of 11

GENERAL INFORMATION [807.92(a)(1)]

Applicant:
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Date Prepared: August 12, 2016

DEVICE INFORMATION [807.92(a)(2)]

The CuraSeal Percutaneous Intraluminal Closure System for Anorectal Fistulas (PICS-AF™) is a medical device consisting of a Sealing Disk, Sheath, Dilator, Collagen Matrices and resorbable sutures. The PICS-AF Closure System is designed as a sphincter-sparing device that inhibits the movement of enteric matter into the anorectal fistula tract and to provide a scaffold for tissue ingrowth to occur to close the anorectal fistula.

Trade Name:
CuraSeal Percutaneous Intraluminal Closure System for Anorectal Fistulas (PICS-AF™)

Generic/Common Name:
Surgical Mesh

Classification:
21 CFR§878.3300, Class II

Product Code:
FTM

PREDICATE DEVICE(S) [807.92(a)(3)] **K162388, pg. 2 of 11**

- W.L. Gore & Associates, GORE BIO-A Fistula Plug (K083266)
- Cook Biotech, SIS Fistula Plug (K050337)

The Cook Biotech, SURGISIS® RVP™ Recto-Vaginal Fistula Plug (K062729) is added as a reference device due to its same intended use and similar technological characteristics.

The predicate devices have not been subject to a design-related recall.

DEVICE DESCRIPTION [807.92(a)(4)]

The PICS-AF Closure System is a sterile, single-use medical device that is designed to be implanted, using a minimally invasive surgical technique, to reinforce soft tissue for the repair of anal and rectal fistulas like the predicate devices. As the PICS-AF Closure System is specifically designed to be sphincter sparing, it does not preclude performing a repeat PICS-AF procedure or any other fistula repair procedure, if required. The key features of the CuraSeal PICS-AF Closure System include the Sealing Disk, Sheath, Dilator, Collagen Matrices and resorbable sutures. There are two models of the PICS-AF device (M1 and M2). Model M1 has a smaller Sealing Disk and smaller diameter Collagen Matrices than Model M2. The Collagen Matrices consist of up to six collagen dowels that are implanted in the fistula tract. After placement, any excess collagen dowels are removed or trimmed at the time of surgery. Placement of the PICS-AF device to cover the inner ostium opening of the fistula tract inhibits the movement of enteric matter into the fistula tract and the collagen provides a scaffold for wound healing to occur to close the anorectal fistula. The Collagen Matrices are delivered directly into the fistula tract and are secured to the fistula tract or the surrounding tissue by resorbable sutures. The Collagen Matrices are resorbed by the body during the natural healing process. The silicone Sealing Disk is designed to be expelled from the body as waste once the resorbable sutures have resorbed. Alternatively, the silicone Sealing Disk can be removed by the physician during the first two months following the procedure if the Sealing Disk appears in the patient's anal canal or causes any discomfort. Similar to the predicate devices, the external fistula opening (EFO) is left open during the healing process to allow for drainage to prevent infection or abscess formation.

INDICATIONS FOR USE [807.92(a)(5)]

The CuraSeal Percutaneous Intraluminal Closure System for Anorectal Fistulas (PICS-AF™) is for implantation to reinforce soft tissue for the repair of anal and rectal fistulas.

TECHNOLOGICAL CHARACTERISTICS [807.92(a)(6)]

The technological characteristics of the CuraSeal PICS-AF Closure System are similar and substantially equivalent to the predicate devices. Table 1 lists the technological characteristics of the PICS-AF device and the predicate devices. Table 1 also provides the rationale to support a determination of substantial equivalence. Any differences between the devices do not raise different questions of safety or effectiveness. Performance data, including clinical testing, were provided to support the determination

of substantial equivalence. Clinical testing was performed by CuraSeal. The results from the clinical testing support the safe and effective use of the PICS-AF Closure System for anal and rectal fistula repair and further establish the substantial equivalence to the predicate devices.

Table 1: Summary of Technological Characteristics

Feature	CuraSeal PICS-AF	W.L. Gore & Associates, GORE BIO-A Fistula Plug (Predicate)	Cook Biotech, SIS Fistula Plug (Predicate)	Cook Biotech, Modified SIS Fistula Plug (Reference)	Substantial Equivalence Rationale
510(k) Number	TBD	K083266	K050337	K062729	--
Indications for Use	The CuraSeal Percutaneous Intraluminal Closure System for Anorectal Fistulas (PICS-AF™) is for implantation to reinforce soft tissue for the repair of anal and rectal fistulas.	The GORE BIO-A™ Fistula Plug device is intended for use in the reinforcement of soft tissue for the repair of anorectal fistulas.	The SIS Fistula Plug is for implantation to reinforce soft tissue where a rolled configuration is required, for repair of anal, rectal, and enterocutaneous fistulas. The device is supplied sterile and is intended for one-time use.	The Modified SIS Fistula Plug is for implantation to reinforce soft tissue for repair of recto-vaginal fistulas. The device is supplied sterile and is intended for one-time use.	Like the predicate devices, the PICS-AF device reinforces soft tissue for the repair of anal and rectal fistulas. It is also supplied sterile and is intended for one-time use. The minor differences in the indications for use statements do not affect the safety and effectiveness of the PICS-AF device.
Classification/ Product Code	§878.3300 FTM	§878.3300 FTL	§878.3300 FTM	§878.3300 FTM	Same classification. Same or similar Product Code
Anatomical Location	Anal and rectal fistulas	Anal and rectal fistulas	Anal, rectal, or enterocutaneous fistulas	Rectal and vaginal fistulas	Same or similar anatomical location

Feature	CuraSeal PICS-AF	W.L. Gore & Associates, GORE BIO-A Fistula Plug (Predicate)	Cook Biotech, SIS Fistula Plug (Predicate)	Cook Biotech, Modified SIS Fistula Plug (Reference)	Substantial Equivalence Rationale
	Bovine dermis-derived, cross-linked collagen	Synthetic PGA/TMC copolymer	Porcine-derived small intestine submucosa	Porcine-derived small intestine submucosa	Like the predicate devices, the resorbable material acts as a scaffold to specifically reinforce soft tissue and promote healing of the fistula tract. Design verification and clinical testing demonstrate that the PICS-AF device is safe and performs as intended. The PICS-AF is substantially equivalent to the predicate devices.
Resorbable Plug Shape	Round dowels, segmented up to 6 dowels/device	One piece device consists of Cap and six round hollow tube segments. Tube segments are cut to length and/or cut off to suit fistula diameter.	Tapered rolled sheet, one piece cut to length	Tapered rolled sheet, one piece cut to length	All devices have plugs that occupy the fistula tract and any excess material is trimmed from the device at the time of surgery. The PICS-AF is substantially equivalent to the predicate devices.
Attachment Mechanism	Internal disk and resorbable sutures	Internal cap and resorbable sutures	Resorbable sutures	Internal disk and resorbable sutures	All devices have similar attachment mechanism. Design verification and clinical testing demonstrate that the PICS-AF device is safe and performs as intended. The PICS-AF is substantially equivalent to the predicate devices.

Feature	CuraSeal PICS-AF	W.L. Gore & Associates, GORE BIO-A Fistula Plug (Predicate)	Cook Biotech, SIS Fistula Plug (Predicate)	Cook Biotech, Modified SIS Fistula Plug (Reference)	Substantial Equivalence Rationale
Disk Design	Sealing Disk	Disk	N/A	Button/Flange	Like the GORE BIO-A Fistula Plug, the internal opening of the ostium is closed to mitigate enteric fluids from entering the fistula tract. Design verification and clinical testing demonstrate that the PICS-AF device is safe and performs as intended. The PICS-AF is substantially equivalent to the predicate devices.
Delivery Sheath Design	Protects collagen and keeps it clean when pulled into tract	N/A	N/A	N/A	Design verification and clinical testing demonstrate that the addition of the Sheath/Dilator for the PICS-AF device does not increase the risk to the patient and is therefore substantially equivalent to the predicate devices.
Sterilization Method	Ethylene Oxide Gas	Gamma Irradiation	Ethylene Oxide Gas	Ethylene Oxide Gas	Same sterility assurance level, same or similar sterilization method

SUBSTANTIAL EQUIVALENCE

The indications for use for the CuraSeal PICS-AF Closure System is substantially equivalent to the indications for use of the predicate devices. Any differences in the technological characteristics between the devices do not raise different questions of safety or effectiveness. Thus, the CuraSeal PICS-AF Closure System is substantially equivalent to the predicate devices.

PERFORMANCE DATA [807.92(b)]

All necessary bench and clinical testing were conducted on the CuraSeal PICS-AF Closure System to support a determination of substantial equivalence to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench and clinical testing were conducted on the CuraSeal PICS-AF Closure System to support a determination of substantial equivalence to the predicate devices.

Non-clinical Testing Summary [807.92(b)(1)]:

The non-clinical, bench testing included:

- Design verification and bench validation studies, including dimensional analysis
- Physician simulated use
- Biocompatibility
- Sterilization
- Packaging and shelf-life

The collective results of the non-clinical testing demonstrate that the materials chosen, the manufacturing processes utilized and the design of the CuraSeal PICS-AF Closure System meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrate that the CuraSeal PICS-AF Closure System does not raise different questions of safety or effectiveness for the repair of anorectal fistulas when compared to the predicate devices.

Clinical Testing Summary [807.92(b)(2)]:

A prospective, non-randomized clinical study was conducted to evaluate the safety and effectiveness of the PICS-AF Closure System for repair of anorectal fistulas. The safety and effectiveness rates for the PICS-AF devices were compared to historical control data generated from commercially available anorectal fistula repair devices.

The PICS-AF Closure System was used in 30 subjects enrolled in the study from one clinical site in Europe. Eight different investigators treated the 30 PICS-AF subjects. There were also 19 Historical Control subjects that were treated using a commercially available fistula plug (GORE BIO-A Fistula Plug) at this same clinical site and were evaluated as part of the PICS-AF clinical study.

The primary effectiveness endpoint for this study was fistula closure success at 6 months defined as complete healing of the fistula tract and associated external opening without drainage or abscess. Fistula closure success for the PICS-AF device was assessed using MRIs from Month 6. The MRI results were reviewed and adjudicated by three independent U.S. radiologists. The rate of the PICS-AF closure success at 6 months was 46.67% (14/30) based on the Intent-to-Treat (ITT) population results and 66.67% (14/21) based on the Per Protocol (PP) population results. Nine subjects had inclusion/exclusion deviations, based on the independent MRI assessment, and thus should have been disqualified from participating in the PICS-AF study.

The primary safety endpoint for this study was the proportion of subjects experiencing a serious adverse event (i.e., an infection, enlargement of the fistula, an allergic reaction to the PICS-AF device, etc.) through 6 months of post-procedure follow-up. There were three subjects who experienced a Serious Adverse Event during this study (two subjects had a fistula abscess and the third subject had a seton placed). The two subjects with a fistula abscess have recovered without sequelae and the subject with the seton is stable. The PICS-AF safety results have demonstrated that the overall primary safety endpoint was met. The PICS-AF safety data was comparable to the Historical Control group. The overall PICS-AF adverse event data was 50% as compared to 36.84% for the Historical Controls; however, this difference was not statistically significant (P=0.3955).

Table 2 provides the baseline demographics and characteristics for the control (GORE BIO-A Fistula Plug) and PICS-AF treatment groups.

Table 2: Baseline Demographics and Characteristics

Characteristic	Control N=19	PICS-AF N=30	P-value
Gender: n/N (% Male)	17/19 (89.47%)	23/30 (76.67%)	0.4511[a]
Age: Mean (SD) N Median (Min, Max)	50.11 (7.522) 18[c] 49.5 (35, 64)	53.70 (12.086) 30 56.5 (31, 76)	0.2112[b]
Smoker: n/N (%)	5/19 (26.32%)	11/30 (36.67%)	0.5412[a]
Obese: n/N (%)	4/19 (21.05%)	7/30 (23.33%)	1.0000[a]
Diabetes: n/N (%)	5/19 (26.32%)	2/30 (6.67%)	0.0926[a]

[a]Two-sided Fisher's exact test.
[b]Two-sided unequal variance t-test.
[c]One Historical Control subject did not record age.

Table 3 provides a comparison of the fistula variables at baseline for the control (GORE BIO-A Fistula Plug) and PICS-AF treatment groups.

Table 3: Comparison of Fistula Variables at Baseline

Characteristic	Control N=19	PICS-AF N=30
Onset of Fistula: Mean (Min, Max)	32.6 mo. (5 mo., 121 mo.)	57.2 mo. (4 mo., 246 mo.)
Type of Fistula: Transsphincteric	19/19 (100%)	30/30 (100%)
Length of Fistula Tract (cm): Mean (SD) N Median (Min, Max)	 4.1000 (1.8529) 10[a] 4.00 (2.00, 8.00)	 5.6733 (2.4057) 30 5.25 (2.50, 12.00)
No. of Fistula Openings: n/N (%) Internal 1 opening:	 19/19 (100%)	 30/30 (100%)
Internal 2 openings:	--	--
External 1 opening:	16/19 (84%)	26/30 (87%)
External 2 openings:	3/19 (16%)	4/30 (13%)
Inner Fistula Diameter (cm):	Not Reported	
Mean (SD)	--	0.6017 (0.8391)
Median (Min, Max)	--	0.30 (0.05, 3.80)
Outer Fistula Diameter (cm):	Not Reported	
Mean (SD)	--	0.6137 (0.7834)
Median (Min, Max)	--	0.50 (0.01, 4.00)
Recurrent Fistula: n/N (%)	12/19 (63%)	20/30 (66.67%)
No. of Previous Fistula Treatments	16	93
Incontinence Score: Mean (Min, Max)	Not Performed	
Solid	--	0.23 (0, 4)
Liquid	--	0.67 (0, 4)
Gas	--	0.33 (0, 3)
Wears Pad	--	0.40 (0, 4)
Lifestyle Alteration	--	0.57 (0, 4)
Pain Scale:	Not Performed	
Mean (Min, Max)	--	3.83 (0, 8)

[a]Nine Historical Control subjects did not have fistula length recorded.
Incontinence Scale: 0=Never, 1=Rarely, 2=Sometimes, 3=Usually, 4=Always
Pain Scale: 0-10 (0=No pain, 5=Moderate pain, 10=Worst pain)

Table 4 provides the Month 6 fistula closure results for the control (GORE BIO-A Fistula Plug) and PICS-AF treatment groups.

Table 4: Fistula Closure Results at Month 6

Treatment Group	Fistula Not Closed n/N (%)	Fistula Closed n/N (%)
PICS-AF	16/30 (53.33%)	14/30[a] (46.67%)
Control	17/18[b] (94.44%)	1/18 (5.56%)

[a]Nine subjects were determined to have inclusion/exclusion deviations that were detected by independent MRI readings. These subjects should not have been enrolled into this study. None of these nine subjects had healed fistulas at Month 6. The fistula closure success rate was 14/21 (66.67%) for subjects who met all specified enrollment criteria.
[b]One Historical Control subject did not have an outcome recorded at six months.

Table 5 provides an analysis of the impact on fistula closure results based on the baseline characteristics for the combined treatment groups.

Table 5: Logistic Regression for Baseline Characteristic Impact on Fistula Closure

Baseline Characteristic	Covariate P-value	P-value (Combined Treatment Groups)
Age	0.6973	**0.0179**
Weight	0.3005	**0.0244**
Gender	**0.0400**	**0.0174**
History of Diabetes	0.7948	**0.0176**
History of Cardiac Disease	0.5648	**0.0133**
History of Renal Disease	0.9801	**0.0115**
History of Smoking	0.3127	**0.0111**

Table 6 provides a comparison of Month 6 outcomes for the control (GORE BIO-A Fistula Plug) and PICS-AF treatment groups.

Table 6: Comparison of Month 6 Outcomes

Category	Control N=19	PICS-AF N=30
Fistula Healed: n/N (%)	1/18[a] (5.56%)	14/30 (46.67%)
Incontinence Score: Mean (Min, Max)	Not Performed	
Solid	--	0.27 (0, 3)
Liquid	--	0.97 (0, 4)
Gas	--	1.03 (0, 4)
Wears Pad	--	1.30 (0, 4)
Lifestyle Alteration	--	1.00 (0, 4)
Pain Scale:	Not Performed	
Mean (Min, Max)	--	2.37 (0, 10)

[a]One Historical Control subject did not have an outcome recorded at six months.
Incontinence Scale: 0=Never, 1=Rarely, 2=Sometimes, 3=Usually, 4=Always
Pain Scale: 0-10 (0=No pain, 5=Moderate pain, 10=Worst pain)

Table 7 provides a summary of the adverse events (including serious adverse events) for the control (GORE BIO-A Fistula Plug) and PICS-AF treatment groups.

Table 7: Adverse Events

Adverse Event	Control		PICS-AF	
	Number of Patients n/N (%)	Number of Events	Number of Patients n/N (%)	Number of Events
Primary Safety Endpoint[a]	0/19 (0%)	0	3/30 (10.00%)	3
Any Adverse Event	7/19 (36.84%)	7	15/30 (50.00%)	17[d]
Hypertension	0/19 (0%)	0	1/30 (3.33%)	1
Fistula-related Infection	0/19 (0%)	0	2/30 (6.67%)	2
Skin Irritation	0/19 (0%)	0	1/30 (3.33%)	1
Pain and Discomfort	0/19 (0%)	0	4/30 (13.33%)	4
Other Fistula-related Complication[b]	0/19 (0%)	0	2/30 (6.67%)	2
Premature Pullout of the Anchor Suture and Partial Migration	1/19 (5.26%)	1	0/30 (0%)	0
Fistula Abscess[c]	2/19 (10.53%)	2	1/30 (3.33%)	1
New Fistula	2/19 (10.53%)	2	0/30 (0%)	0
Recurrence of Treated Fistula Tract	1/19 (5.26%)	1	0/30 (0%)	0
Fistula Tract Bleeding	1/19 (5.26%)	1	0/30 (0%)	0
Infection – Fistula Tract	0/19 (0%)	0	1/30 (3.33%)	1
Other	0/19 (0%)	0	2/30 (6.67%)	2

[a]Fistula abscess requiring IV antibiotics and extended hospitalization (SAE).
[b]One mild external orifice and one anal canal ulcer.
[c]Excludes the two fistula abscesses that were primary safety endpoint events.
[d]Two subjects had two Events each.

Table 8 summarizes the PICS-AF fistula healing outcomes based upon: subjects with adverse events and not healed fistulas; subjects with adverse events and healed fistulas; and subjects with no adverse events and not healed fistulas.

Table 8: Summary of PICS-AF Fistula Healing Outcomes at Month 6

PICS-AF Subjects with Adverse Events and Not Healed Fistulas (n=11)					
No. Subjects	**No. Adverse Events**	**No. Serious Adverse Events**	**Type of Intervention n/N (%)**	**Solid Incontinence n/N (%)**	**Pain Scale Score Mean (Min, Max)**
11	11	2	Sealing Disk removed = 3/11 (27%) Setons placed = 1/11 (9%) Drainage performed = 2/11 (18%) Medications prescribed = 3/11 (27%)	0=Never: 8/11 (73%) 1=Rarely: 2/11 (18%) 2=Sometimes: 0/11 (0%) 3=Usually: 1/11 (9%) 4=Always: 0/11 (0%)	3.27 (0, 8)
PICS-AF Subjects with Adverse Events and Healed Fistulas (n=4)					
No. Subjects	**No. Adverse Events**	**No. Serious Adverse Events**	**Type of Intervention n/N (%)**	**Solid Incontinence n/N (%)**	**Pain Scale Score Mean (Min, Max)**
4	3	1	Sealing Disk removed = 1/4 (25%) Setons placed = 0/4 (0%) Drainage performed = 2/4 (50%) Medications prescribed = 3/4 (75%)	0=Never: 4/4 (100%) 1=Rarely: 0/4 (0%) 2=Sometimes: 0/4 (0%) 3=Usually: 0/4 (0%) 4=Always: 0/4 (0%)	3.0 (0, 10)
PICS-AF Subjects with No Adverse Events and Not Healed Fistulas (n=5)					
No. Subjects	**No. Adverse Events**	**No. Serious Adverse Events**	**Type of Intervention n/N (%)**	**Solid Incontinence n/N (%)**	**Pain Scale Score Mean (Min, Max)**
5	0	0	Sealing Disk removed = 0/5 (0%) Setons placed = 0/5 (0%) Drainage performed = 0/5 (0%) Medications prescribed = 0/5 (0%)	0=Never: 5/5 (100%) 1=Rarely: 0/5 (0%) 2=Sometimes: 0/5 (0%) 3=Usually: 0/5 (0%) 4=Always: 0/5 (0%)	1.6 (0, 5)

In conclusion, the collective data from the PICS-AF Clinical Study support the overall safety and effectiveness of the PICS-AF Closure System for the repair of anorectal fistulas. The PICS-AF Closure System has been demonstrated to have favorable effectiveness results for fistula closure and to have an acceptable safety profile.

CONCLUSIONS [807.92(b)(3)]

Extensive bench and clinical testing have been performed on the CuraSeal PICS-AF Closure System to evaluate the overall performance of the device. The collective results confirm that the CuraSeal PICS-AF Closure System is safe and effective, functions according to its specifications, is biocompatible and exhibits the appropriate mechanical and functional characteristics for an anorectal fistula repair device.

SUMMARY

The CuraSeal PICS-AF Closure System is considered to be substantially equivalent to the predicate devices.