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

April 13, 2017

Halyard Health, Inc.
Monica King
Associate Director, Regulatory Affairs
5405 Windward Parkway
Alpharetta, Georgia 30004

Re: K163461
Trade/Device Name: Coolief* Cooled RF Probe
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
Dated: March 13, 2017
Received: March 14, 2017

Dear Ms. King:

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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K163461

Device Name
COOLIEF* Cooled RF Probe

Indications for Use *(Describe)*
The COOLIEF* Cooled Radiofrequency Probe is to be used in conjunction with a radiofrequency generator to create lesions in nervous tissue. This device is also indicated for creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response (≥50% reduction in pain) to a diagnostic genicular nerve block.

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 as Required by 21 CFR §807.92(c)

As required by the Safe Medical Devices Act (SMDA) of 1990 and in accordance with 21 CFR §807.92(a), the 510(k)-summary provided below is of sufficient detail to provide an understanding of the basis for a determination of substantial equivalence.

510(k) Summary

1. Contact Details

Date Summary Prepared	04/05/2017
510(k) Applicant Name, Address, Website	Halyard Health, Inc. 5405 Windward Parkway Alpharetta, GA 30004 www.halyardhealth.com
Applicant Contact Person	Monica King Associate Director, Regulatory Affairs Phone: (678) 477-4165 FAX: (678) 254-0347 Email: monica.king@hyh.com

2. Device Information

Trade Name	COOLIEF* Cooled RF Probe
Common Name	Radiofrequency Lesion Probe
Models	CRP-, CRK-, MCK-
Classification	II
Classification Name	Probe, Radiofrequency Lesion
Regulation Number	21 CFR §882.4725
Product Code	GXI
Review Panel	84 Neurology

3. Legally Marketed Predicate Device:

Trade Name	Pain Management Cooled Probe
510(k) Number	K053082
Product Code	GXI
Manufacturer	Halyard Health

4. Description of Device:

The COOLIEF* Cooled Radiofrequency (RF) Probe is a sterile, single-use device that delivers RF energy within the area of the active probe tip, while the probe tip is cooled by sterile water that circulates within the probe. Cooling the probe tip creates a larger, more homogenous RF heating area that results in a larger RF lesion in the target tissue. COOLIEF* Cooled RF Probe is used in conjunction with the Halyard RF Generator to create RF lesions in nervous tissue. The shaft of the probe is insulated with a polyimide sheath, and the distal tip consists of a medical grade stainless steel electrode. Sterile water circulates through a cavity in the electrode to cool the electrode tip during the cooled RF ablation procedure. The COOLIEF* Cooled Radiofrequency (RF) Probe is sterilized by ethylene oxide.

Proposed Indication for Use:

The COOLIEF* Cooled Radiofrequency Probe is to be used in conjunction with a radiofrequency generator to create lesions in nervous tissue. This device is also indicated for creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response (≥50% reduction in pain) to a diagnostic genicular nerve block.

5. Substantial Equivalence Comparison

The following table compares the subject COOLIEF* Cooled RF Probe to the predicate Pain Management Cooled Probe (K053082) to support substantial equivalence.

Characteristic	COOLIEF* Cooled RF Probe (K163461)	Pain Management Cooled Probe (K053082)	Comments
Intended Use	The COOLIEF* Cooled Radiofrequency Probe is to be used in conjunction with a radiofrequency generator to create lesions in nervous tissue. This device is also indicated for creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response (≥50% reduction in pain) to a diagnostic genicular nerve block.	Used in conjunction with a radiofrequency generator to create radiofrequency lesions in nervous tissue.	Clinical data to support the proposed indication is submitted in the Protocol *A Prospective, Multi-center, Randomized, Clinical Trial Evaluating the Safety and Effectiveness of Using Coolief™ Cooled Radiofrequency Probe to Create Lesions of the Genicular Nerves and Comparing Corticosteroid Injection in the Management of Knee Pain*
Probe Shaft Length	Overall Useable Length 150mm, 100mm, 75mm, 50mm Shaft Outer Diameter 18Ga	Overall Useable Length 150mm, 100mm, 75mm, 50mm Shaft Outer Diameter 18Ga	Equivalent
Distal Tip Length	6mm probe electrode with various active lengths when combined with a mating introducer of 2, 4, and 5.5mm	6mm probe electrode with various active lengths when combined with a mating introducer of 2, 4, and 5.5mm	Equivalent
Lesion Size	10-12mm, Spherical	10-12mm, Spherical	Equivalent
Temperature Measurement Accuracy	± 3° C	± 3° C	Equivalent
Temperature Measurement Device	Thermocouple	Thermocouple	Equivalent

Characteristic	COOLIEF* Cooled RF Probe (K163461)	Pain Management Cooled Probe (K053082)	Comments
Temperature Range	38° - 95° C	38° - 95° C	Equivalent
Temperature Increment	1°C	1°C	Equivalent
Single Use	Yes	Yes	Equivalent
Compatible RF System	Halyard COOLIEF* System Only	Halyard COOLIEF* System Only	Equivalent
Disposable	Yes	Yes	Equivalent
Biocompatibility	Conforms to ISO10993	Conforms to ISO10993	Equivalent
Sensitization ISO 10993-10	Conforms to ISO10993-10	Conforms to ISO10993-10	Equivalent
Irritation ISO 10993-20	Conforms to ISO10993-20	Conforms to ISO10993-20	Equivalent
Cytotoxicity ISO 10993-5	Conforms to ISO10993-5	Conforms to ISO10993-5	Equivalent

Characteristic	COOLIEF* Cooled RF Probe (K163461)	Pain Management Cooled Probe (K053082)	Comments
Systemic toxicity ISO 10993-11	Conforms to ISO10993-11	Conforms to ISO10993-11	Equivalent
Sterility	Sterilized by EO $SAL = 10^{-6}$	Sterilized by EO $SAL = 10^{-6}$	Equivalent
Packaging	Device contained in a single use Tyvek sealed tray	Device contained in a single use Tyvek sealed tray	Equivalent

The difference in the Indications for Use statements do not raise new questions of safety and effectiveness. Cooled radiofrequency (RF) is a well-established method for delivering lesions into nervous tissue to accomplish neurotomy procedures. The use of the Cooled RF probe to perform the genicular neurotomy procedure is like the other minimally invasive cooled radiofrequency ablation procedures in that lesions are created in targeted sensory nerves to block the transmission of pain signals. The RF lesions created in the genicular neurotomy procedure are the same size and shape as in other RF procedures. The clinical data collected to support the proposed indication demonstrate that the COOLIEF* Cooled RF Probe does not present safety or effectiveness issues related to the proposed indication for use. Data collected at the primary endpoint supports the conclusion that the COOLIEF* Cooled RF Probe used for genicular nerve ablation is superior to corticosteroid injection in osteoarthritic subjects for managing knee pain.

Reference Device

A reference device is presented below regarding the biocompatibility data set for this device. Biocompatibility testing data is derived from testing conducted on the representative Halyard* TransDiscal* RF probe (K031951): the TransDiscal* RF probe and the Cooled Radiofrequency Probe are composed of the same raw materials, manufactured using similar processes within the same facility, sterilized using the same Ethylene Oxide cycles and chambers, and packaged using the same packaging materials.

Comparison to Reference Device	
Subject Device: COOLIEF* Cooled RF Probe	Reference Device: TransDiscal* RF probe
K163481	**K031951**
The COOLIEF* Cooled Radiofrequency Probe is to be used in conjunction with a radiofrequency generator to create lesions in nervous tissue. This device is also indicated for creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response (≥50% reduction in pain) to a diagnostic genicular nerve block.	The Transdiscal system, in combination with the Baylis Pain Management Generator-TD (PMG-TD), is indicated for the coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs.
Sterility: Sterilized by EO SAL = 10^{-6}	Sterility: Sterilized by EO SAL = 10^{-6}
Packaging: Device contained in a single use Tyvek sealed tray	Packaging: Device contained in a single use Tyvek sealed tray

6. Non-Clinical Testing

The table below describes the test type, standard reference, acceptance criteria, and result summary.

Biocompatibility Testing

Test Type	Standard	Test Name	Criteria	Result
Cytotoxicity	ISO 10993-5	In Vitro Cytotoxicity, Direct and Extract	Qualitative Grade = 0 Quantitative = cell death < 30%	Pass: No Cytotoxic effect
Sensitization	ISO 10993-10	In Vivo, Animal GPMT	Challenge Phase = Less than Grade 1 and less than the controls	Pass: No signs of sensitization
Irritation or Intracutaneous reactivity	ISO 10993-10	In Vivo, Animal Irritation (Rabbits)	Test sample score ≤ 1.0 for Erythema and Edema grading	Pass: No signs of Irritation
Systemic Toxicity (acute)	ISO 10993-11	In Vivo, Animal Toxicity (Mice)	No animal death	Pass: No signs of systemic toxicity

Summary of IEC 60601 Compliance

Test	Test Description	Results
Electrical safety	IEC 60601-1:2005 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	Passed
High Frequency surgical equipment	IEC 60601-2-2: 2009 (Fifth Ed.) Medical electrical equipment Part 2-2: Requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	Passed
Electromagnetic Compatibility (EMC)	IEC 60601-1-2:2007 / AC 2010 Medical electrical equipment Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility	Passed

7. Clinical Testing

Halyard conducted a prospective, multicenter, randomized comparative human study, to confirm the safety and effectiveness of COOLIEF* Cooled RF Probe for creating lesions of the genicular nerves for pain management of the knee. The COOLIEF* Cooled RF Probe was compared to corticosteroid injection.

The primary effectiveness endpoint of the clinical study was the proportion of subjects whose knee pain is reduced by ≥ 50% based on the Numeric Rating Scale (NRS) at the 6-month study time point. At the 6-month study time point, based on Intention to Treat (ITT) ≥50% pain relief over baseline was experienced by 67.2% of the COOLIEF* Cooled RF study group vs. 15.7% of the comparison group (i.e., corticosteroid injection), using the Numeric Rating Scale (Pain rating scale 1 to 10).

Significant and sustained pain reduction was observed in the study group: subjects had a 4.9-point mean drop in NRS from a baseline mean of 7.3 to a mean of 2.5 at 6 months, while the comparison group had a 1.3-point mean drop in NRS from a baseline of 7.2 to a mean of 5.9 at 6 months. Significant functional improvement occurred in the study group: 39.7% reported “Satisfactory Joint Function” vs. 3% in comparison group. Global Perceived Effect Knee condition was reported as “improved” in 91.4% of the study group vs. 23.9% in the comparison group.

Adverse Events

The proportion of study subjects that had adverse events (AEs) in each cohort was: CRFA, 45% (34/76); IAS, 40% (30/75). The number of AEs reported in each study group was similar (CRFA = 61 events, IAS = 65 events). Most AEs during the study were non-serious, mild or moderate in severity, and were determined to be not related to study treatment. The AEs with Possible, Probable, or Definite relationship to procedure are:

    - CRFA Group (14 events in 13 subjects): post-procedure pain (9 events), ecchymosis (1), pruritic skin lesion (1), swelling and redness - infection (1), mild tenderness to touch (1), increased knee pain - severe (1)
    - IAS Group (2 events in 2 subjects): white discoloration at injection site (1), fluctuating blood sugar levels (1)
- Post-procedural "fall" incidence:
    - CRFA Group (2 events in 1 subject)
    - IAS Group (4 events in 4 subjects)
- Serious AEs:
    - CRFA Group (4 events in 2 subjects): 1) pyelonephritis, 2) exacerbation of asthma, 3) severe acute asthma, and 4) acute respiratory failure
    - IAS Group (8 events in 7 subjects): 1) opioid overdose, 2) heart attack (two subjects), 3) death, 4) nausea and vomiting, 5) worsening of hiatal hernia, 6) gastric volvulus, and 7) abdominal pain secondary to small bowel obstruction.

Medication Use

The study demonstrated a reduction in non-opioid pain medication that was consistent with the clinically relevant improvements demonstrated in the primary endpoint. Table 76 below describes the pain medication usage for subjects taking non-morphine medication at the baseline through 6 months' visits.

Table 76. Pain Medication Usage for Subjects Taking Non-Morphine Pain Medication at Any Visit Through 6 Months – TDD

	Baseline		1 Month		3 Month		6 Month	
	CRFA	IAS	CRFA	IAS	CRFA	IAS	CRFA	IAS
Non-Morphine Pain Medication Usage - Total Daily Dose (mg)								
N	33	35	33	34	32	34	29	35
Mean	899.5	497.4	899.5	537.9	865.2	561.2	834.8	621.4
SD	625.1	437.3	625.1	484.4	636.4	461.4	682.0	497.5
Median	700.0	470.0	700.0	472.5	675.0	498.0	650.0	545.0
Minimum	150.0	0.0	150.0	0.0	150.0	0.0	0.0	0.0
Maximum	3000.0	2000.0	3000.0	2000.0	3000.0	2000.0	3000.0	2000.0
Difference between means (CRFA-IAS) and 95% CI	402.1 (138.7, 665.5)		361.7 (89.3, 634.0)		304.0 (31.8, 576.1)		213.5 (-81.7, 508.6)	
P-value (difference between groups)	0.0012**		0.0038**		0.0250**		0.2143**	
Change from Baseline in Non-Morphine Pain Medication Usage - Total Daily Dose (mg)								
N	--	--	33	34	32	34	29	35
Mean	--	--	0.0	44.9	-15.6	60.9	-34.5	123.9
SD	--	--	0.0	226.3	88.4	277.7	128.9	375.4
Median	--	--	0.0	0.0	0.0	0.0	0.0	0.0
Minimum	--	--	0.0	0.0	-500.0	0.0	-500.0	-440.0
Maximum	--	--	0.0	1307.5	0.0	1600.0	0.0	1600.0
Difference between means (CRFA-IAS) and 95% CI	--	--	-44.9 (-124, 34.0)		-76.5 (-178, 24.8)		-158 (-295, -21.7)	
P-value (difference between groups)	--	--	0.1668**		0.0506**		0.0229**	
P-value (change from Baseline)	--	--	--	0.2552$	0.3251$	0.2100$	0.1609$	0.0591$

Table displays total daily dose of non-morphine pain medication for the subjects taking non-morphine pain medication at any follow-up visit. Subjects with only the Baseline visit are excluded.
**T-test for two independent means, **Wilcoxon rank sum test for two independent samples, $paired t-test*

Program: HYH03 output TDD Non-Morphine At Any Visit 6M.sas
Data Source: hyh03_painmedsub]
Date Run: 01MAR2017 - 15:36

An analysis of the primary endpoint for the patients who were opioid dependent at baseline and were evaluated for the primary endpoint demonstrated that there was no relationship between outcome and opioid status as described in Table 82 below. Of the 43 Cooled Radiofrequency Ablation (CRFA) successes, only 10 patients were on opioids at Baseline (23.3%) as compared to 46.7% of the CRFA group who failed the primary endpoint (7/15). Overall, opioid status did not influence the outcomes (p= 0.4073).

Table 82: Primary Endpoint Success or Failure for Subjects Taking Opioids at Baseline n/N%

	Cooled Radiofrequency Ablation (CRFA)	**Intraarticular Steroid (IAS)**	**Overall**
Subjects that are Primary Endpoint success	10/43 (23.3)	5/11 (45.5)	15/54 (27.8)
Subjects that are Primary Endpoint failure	7/15 (46.7)	18/57 (31.6)	25/72 (34.7)
P-value	0.1073†	0.4889†	0.4073††

†Fisher exact test for proportions, ††Chi-square test for proportions

The results of the pre-planned statistical analysis of the primary endpoint supports the conclusion that the COOLIEF* Cooled Radiofrequency Probe used for genicular nerve ablation is superior to corticosteroid injection in osteoarthritic subjects for managing knee pain.

8. Conclusion

The non-clinical data demonstrate that the COOLIEF* Cooled RF probe devices perform equivalently to the predicate device that is currently marketed. The clinical data demonstrate that the COOLIEF* Cooled RF probe does not present safety or effectiveness issues related to the proposed indication for use. Data collected at the primary endpoint supports the conclusion that the COOLIEF* Cooled Radiofrequency Probe used for genicular nerve ablation is superior to corticosteroid injection in osteoarthritic subjects for managing knee pain. The change to the indications for use does not raise different questions of safety or effectiveness.

End of 510(k) Summary