May, 26 2026

STARmed Co.,Ltd.
% Daniel Dillon
Senior Regulatory Scientist
MED Institute
1330 Win Hentschel Blvd., Suite 100
West Lafayette, Indiana 47906

Re: K252833
Trade/Device Name: VIVA combo RF System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 4, 2025
Received: September 5, 2025

Dear Daniel Dillon:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.05.26 18:19:10 -04'00'

Colin Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K252833

Device Name

VIVA combo RF System

Indications for Use *(Describe)*

The VIVA combo RF generator, star RF Electrodes, and VIVA RF Electrodes are indicated for percutaneous and interoperative coagulation and ablation of tissue, including ultrasound-guided percutaneous ablation of cytologically-confirmed benign thyroid nodules in adults that are symptomatic, cosmetically concerning, and/or autonomously functioning. Autonomously functioning nodules are indicated if nodule volume is < 10 mL.

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.

510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR 807.92.

1. Date Prepared

May 18, 2026

2. Submitter's Information

Name of Sponsor:	STARmed Co., Ltd.
Address:	B-dong, 4F&12F, 158, Haneulmaeul-ro, IlsanDong-gu, Goyang-si, Gyeonggi-do, Republic of Korea
Contact Name:	Honggeun Lee Telephone #: +82-10-2363-4998 Fax #: +82-31-816-4546 Email: lhg1186@starmed4u.com
Registration Number:	3013557681
Name of Manufacturer:	STARmed Co., Ltd.

3. Device information

Trade Name:	VIVA combo RF System
Common Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation Number:	21 CFR 878.4400
Product Code:	GEI
Device Class:	II

4. Predicate Devices

- VIVA combo RF generator: 510(k) No. K234140, cleared January 30, 2024
- star RF electrodes and VIVA RF electrodes: 510(k) No. K203795, cleared April 01, 2021

5. Description of the Device

The VIVA combo RF System consists of an RF generator, active electrodes, a grounding pad and a peristaltic pump for electrode cooling.

The VIVA combo RF generator is designed to produce local tissue heating at the tip of the electrodes, causing the coagulation and ablation of tissue. The VIVA combo RF generator is capable of delivering up to 200 W of RF power and the available power is limited through software control. This system monitors power, resistance, current, and temperature. The VIVA combo RF generator also includes software that continuously monitors impedance, current, power and temperature. The unit automatically monitors rises in impedance and adjusts RF output accordingly.

The star RF Electrodes and VIVA RF Electrodes are sterile, single-use electrosurgical accessories intended to be used in conjunction with the VIVA combo RF generator. They are not intended to function with other RF generators. Cooling of the electrode is provided by chilled water, which is pumped through the inflow tubing, through the electrode, and out through the outflow tubing. The system is enclosed within the electrode; the water for cooling is not in contact with the patient. All electrodes use stainless steel 304 for the electrode tip.

The main differences between the various star RF Electrodes and VIVA RF Electrodes are: (a) handle design, (2) insulating material, and (3) size (i.e., electrode length, tip length, and/or diameter (gauge)). VIVA RF Electrodes have an adjustable tip length and are available in three subtypes: VIVA RF Electrode, VIVA RF Electrode V2 type and VIVA RF Electrode V2-T. The differences among electrodes do not impact product performance and safety.

For the benign thyroid nodule indication, the clinically supported electrode configuration consists of the VIVA combo RF Generator used with star RF Electrodes and VIVA RF Electrodes in monopolar mode with continuous radiofrequency power using electrodes with 18–19G diameter, 50–100 mm electrode length, and 4–15 mm exposed tip length at RF power settings of 5–80 W. Electrodes with variable tip exposure lengths greater than 15 mm, including VIVA RF Electrodes, VIVA RF V2 Electrodes, and VIVA RF V2-T Electrodes, should not be extended beyond 15 mm during benign thyroid nodule ablation procedures.

6. Indications for Use

The VIVA combo RF System is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.

The VIVA combo RF generator, star RF Electrodes, and VIVA RF Electrodes are indicated for ultrasound-guided percutaneous ablation of cytologically-confirmed benign thyroid nodules in adults that are symptomatic, cosmetically concerning, and/or autonomously functioning. Autonomously functioning nodules are indicated if nodule volume is < 10 mL.

7. Substantial equivalence comparison

Generator

Parameter	VIVA combo RF generator (This submission)	VIVA combo RF generator (K234140)	Comment
General			
Common Name	Electrosurgical generator	Electrosurgical generator	Same
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories	Same
Classification Panel	General and Plastic Surgery	General and Plastic Surgery	Same
Classification Regulation	21 CFR 878.4400	21 CFR 878.4400	Same
Product Code	GEI	GEI	Same
Device Class	Class II	Class II	Same
Intended Use	The VIVA combo RF System is intended for use in percutaneous and intraoperative coagulation and ablation of tissue. The VIVA combo RF System is indicated for ultrasound-guided percutaneous ablation of cytologically-confirmed benign thyroid nodules in adults that are symptomatic, cosmetically concerning, and/or autonomously functioning. Autonomously functioning nodules are indicated if nodule volume is < 10 mL.	The VIVA combo RF System is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.	Expanded, but substantially equivalent.

Parameter	VIVA combo RF generator (This submission)	VIVA combo RF generator (K234140)	Comment
Intended user profile	General profile listed at right, plus: The American Thyroid Association recommends a practitioner should be certified or board eligible in Otolaryngology Head and Neck Surgery, Interventional Radiology, General Surgery with a focus in Endocrine Surgery, or Endocrinology and have extensive background knowledge and clinical experience in (1) the clinical diagnosis and treatment of thyroid nodules, (2) neck imaging anatomy, (3) thyroid ultrasound imaging and fine needle aspiration biopsy procedures, and (4) ultrasound risk stratification for benign and malignant thyroid tumors.	General profile: • A licensed physician. • Knowledge of the side effects or complications due to errors of the medical device. • Clinical expertise, with appropriate literature or by training. • Understands the manual. • Understands the meaning of the abbreviations. • Procedure performance and specific technology training. • Device usage and safety training.	Similar, but more specific, supporting the more specific intended use.
Prescription or OTC	Prescription	Prescription	Same
Electrical			
Energy Used	Radiofrequency	Radiofrequency	Same
Output Frequency	480 kHz ± 10 %	480 kHz ± 10 %	Same
Drive on Time	Up to 30 minutes	Up to 30 minutes	Same
Maximum Power Output	Up to 200 watts @ 50 ohms	Up to 200 watts @ 50 ohms	Same
Cut-Off in temperature mode	at 15 ohms		Same
Impedance Monitoring	Available	Available	Same
Temperature Monitoring	Available	Available	Same
Software			
S_VCS_B Version	1.11F	1.11F	Same
MRFALogger Version	1.41	1.41	Same
STAR Logger Version	1.30	1.30	Same

Parameter	VIVA combo RF generator (This submission)	VIVA combo RF generator (K234140)	Comment
Other			
Dimension (W x L x H)	260 x 348 x 115 mm	260 x 348 x 115 mm	Same
Isolation of USB/Foot Switch PCB?	Yes	Yes	Same
Fuse	F 5AH 250 V	F 5AH 250 V	Same
Peristaltic Pump Model	VP01 and VP01-1	VP01 and VP01-1	Same
Hospital-grade power cable	Included	Included	Same
Foot Switch Connect Type	Female	Female	Same

As noted, there are no changes in the technology of the device, only the indications for use and, to support the indications for use, the intended user. However, the two devices have the same intended use: RF ablation. Thus, the subject device is substantially equivalent to the predicate device.

Electrodes

Parameter	star Electrodes/ VIVA Electrodes (This submission)	Predicate Device Star RF Electrode, VIVA RF Electrode (K203795)	Reference Device 1 Star RF Electrode, VIVA RF Electrode (K172012)	Reference Device 2 VIVA Combo RF System (K163450)	Comment
General					
Common Name	RF electrosurgical electrode	RF electrosurgical electrode	RF electrosurgical electrode	RF electrosurgical electrode	Same
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories	Same
Classification Panel	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery	Same
Classification Regulation	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	Same
Product Code	GEI	GEI	GEI	GEI	Same

Parameter	star Electrodes/ VIVA Electrodes (This submission)	Predicate Device Star RF Electrode, VIVA RF Electrode (K203795)	Reference Device 1 Star RF Electrode, VIVA RF Electrode (K172012)	Reference Device 2 VIVA Combo RF System (K163450)	Comment
Device Class	Class II	Class II	Class II	Class II	Same
Intended Use	star RF electrodes and VIVA RF electrodes are intended for use in percutaneous and intraoperative coagulation and ablation of tissue. star RF electrodes and VIVA RF electrodes indicated for ultrasound-guided percutaneous ablation of cytologically-confirmed benign thyroid nodules in adults that are symptomatic, cosmetically concerning, and/or autonomously functioning. Autonomously functioning nodules are indicated if nodule volume is < 10 mL.	star RF electrodes and VIVA RF electrodes intended for use in percutaneous and intraoperative coagulation and ablation of tissue.	star RF electrodes and VIVA RF electrodes intended for use in percutaneous and intraoperative coagulation and ablation of tissue.	star RF electrodes intended for use in percutaneous and intraoperative coagulation and ablation of tissue.	Expanded, but substantially equivalent.

Parameter	star Electrodes/ VIVA Electrodes (This submission)	Predicate Device Star RF Electrode, VIVA RF Electrode (K203795)	Reference Device 1 Star RF Electrode, VIVA RF Electrode (K172012)	Reference Device 2 VIVA Combo RF System (K163450)	Comment
Intended user profile	General profile listed at right, plus: The American Thyroid Association recommends a practitioner should be certified or board eligible in Otolaryngology Head and Neck Surgery, Interventional Radiology, General Surgery with a focus in Endocrine Surgery, or Endocrinology and have extensive background knowledge and clinical experience in (1) the clinical diagnosis and treatment of thyroid nodules, (2) neck imaging anatomy, (3) thyroid ultrasound imaging and fine needle aspiration biopsy procedures, and (4) ultrasound risk stratification for benign and malignant thyroid tumors.	General profile: • A licensed physician. • Knowledge of the side effects or complications due to errors of the medical device. • Clinical expertise, with appropriate literature or by training. • Understands the manual. • Understands the meaning of the abbreviations. • Procedure performance and specific technology training. Device usage and safety training.	General profile: • A licensed physician. • Knowledge of the side effects or complications due to errors of the medical device. • Clinical expertise, with appropriate literature or by training. • Understands the manual. • Understands the meaning of the abbreviations. • Procedure performance and specific technology training. Device usage and safety training.	General profile: • A licensed physician. • Knowledge of the side effects or complications due to errors of the medical device. • Clinical expertise, with appropriate literature or by training. • Understands the manual. • Understands the meaning of the abbreviations. • Procedure performance and specific technology training. Device usage and safety training.	Similar, but more specific, supporting the more specific intended use.
Prescription or OTC	Prescription	Prescription	Prescription	Prescription	Same
Electrical/mechanical					
Energy Used	Radiofrequency	Radiofrequency	Radiofrequency	Radiofrequency	Same
Operation Principle	Monopolar	Monopolar	Monopolar	Monopolar	Same
Patient Contacting Materials	Stainless steel 304	Stainless steel 304	Stainless steel 304	Stainless steel 304	Same

Parameter	star Electrodes/ VIVA Electrodes (This submission)	Predicate Device Star RF Electrode, VIVA RF Electrode (K203795)	Reference Device 1 Star RF Electrode, VIVA RF Electrode (K172012)	Reference Device 2 VIVA Combo RF System (K163450)	Comment
Insulation Materials	star RF: Polyester VIVA RF: Polyimide	star RF: Polyester VIVA RF: Polyimide	star RF: Polyester VIVA RF: Polyimide	star RF: Polyester	Same as predicate
Sterile	EO Sterilization	EO Sterilization	EO Sterilization	EO Sterilization	Same
Single Use	Single Use	Single Use	Single Use	Single Use	Same
Connector Type	4 pin	4 pin	4 pin	4 pin	Same
Tubing set	star RF and VIVA RF (standard): Separate from electrode VIVA RF V2/V2-T: Integrated with electrode	star RF and VIVA RF (standard): Separate from electrode VIVA RF V2: Integrated with electrode	star RF and VIVA RF (standard): Separate from electrode	star RF and VIVA RF (standard): Separate from electrode	Same as predicate
Sizes					
Diameter (gauge)	star RF: 18-19 VIVA RF/VIVA RF V2: 18 VIVA RF V2-T: 18-19	star RF: 17-19 VIVA RF/VIVA RF V2: 15-18	star RF: 17-18 VIVA RF: 15-17	star RF: 17	Subset of existing electrodes and addition of a variation.
Electrode length (mm)	star RF/VIVA RF/VIVA RF V2: 70-100 VIVA RF V2-T: 50-100	star RF: 70-350 VIVA RF/VIVA RF V2: 70-200	star RF: 70-200 VIVA RF: 150-200	star RF: 150-200	
Tip exposure length/ exposure length range (mm)	star RF: 4-10 VIVA RF/VIVA RF V2: 5-30 (by 5) VIVA RF V2-T: 5-15 (by 2.5)	star RF: 4-10 VIVA RF/VIVA RF V2: 5-30 (by 5)	star RF: 4-30 VIVA RF: 5-30 (by 5)	star RF: 30	

The indications for use have changed and, to support the indications for use, the intended user. However, the two devices have the same intended use: RF ablation. The electrodes are the same, except for the addition of a minor design variation, the VIVA RF Electrode V2-T, which is similar to VIVA RF Electrode V2, except (1) the range for tip exposure is narrower, (2) the increment for tip exposure is smaller, and (3) it is available in 19 gauge diameters and 50 mm electrode lengths. These differences are considered minor, do not raise any new questions of safety and effectiveness, and the data included in this submission demonstrate that these electrodes are as safe and effective as the predicate electrodes. Thus, the subject device is substantially equivalent to the predicate device.

8. Summary of Non-Clinical Testing

No changes have been made to the technological characteristics of the subject devices compared to the predicate devices, except for the addition of VIVA RF Electrode V2-T electrodes, a minor design variation. The following tests were carried out to evaluate the performance of existing electrodes:

Performance

- Electric Conduction Test
- Flow rate Test
- Welding strength
- Shaft strength
- Drop Test
- Temperature Test
- Impedance test
- Dimension test
- Adjustable Length test
- Durability of the pump tubing
- Ex Vivo - Thermal Effects of Tissue
- Compatibility with substances that come into Contact when using electrodes

Biocompatibility testing

- ISO 10993-5: Biological evaluation of medical devices - Tests for in vitro cytotoxicity.
- ISO 10993-10, ISO 10993-23: Biological evaluation of medical devices - Tests for irritation and skin sensitization.
- ISO 10993-11: Biological evaluation of medical devices - Tests for systemic toxicity.

Sterilization and shelf-life

- ISO 11135:2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical device

- ISO 10993-7: Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.
- ASTM F1980-02: Standard Guide for Accelerated Aging of Sterile Medical Device Packages
- ISO 11607-1: Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

9. Animal Study

No animal studies were necessary to establish substantial equivalence.

10. Clinical Studies

No clinical studies were necessary to establish substantial equivalence. A systematic literature review was conducted to demonstrate the safety and effectiveness of the subject device for its proposed intended use.

Rationale and clinical questions. Benign thyroid nodules (BTNs) may require treatment if they are symptomatic or autonomously functioning. Minimally invasive ultrasound-guided radiofrequency ablation (RFA) has been employed as an alternative to surgery for BTNs requiring treatment, as reported extensively in the literature, including for the subject device (STARmed VIVA combo RF System). A systematic literature review was therefore conducted, with the aim (rationale) of systematically searching, reviewing, summarizing, and evaluating available literature describing (1) percutaneous RFA of BTNs in adults within the context of the state of the art (SOTA) in medicine, and (2) the safety and effectiveness of the STARmed VIVA combo RF System for RFA of BTNs in adults. The primary clinical questions addressed in the SOTA review were whether RFA is an accepted safe and effective alternative to surgery or other treatments and what constituted current clinical benchmarks for safety and effectiveness of RFA of BTNs. The primary clinical question addressed in the subject device SLR was to determine whether the subject device demonstrates comparable safety and effectiveness relative to the benchmarks for RFA of BTNs as identified in the SOTA review.

Search and selection strategy. For the SOTA review, a comprehensive literature search was performed in Embase, PubMed/MEDLINE, and relevant medical society websites. Search strategies used relevant keywords. For example, the following terms were used for the Embase search: ('radiofrequency ablation' OR 'RF ablation' OR (radiofrequency AND treatment)) AND ('benign thyroid nodule' OR 'thyroid nodule' OR (benign AND thyroid)). Results were selected for further evaluation if the publication described diagnostic, treatment, management, or monitoring options for adult patients with BTNs.

For the subject device search, device-specific terms (e.g., “STARmed”, “VIVA”) were searched in Embase, PubMed Central, and Google Scholar in combination with terms related to BTNs. For example, the following terms were used for the PubMed Central search: ("STARMED" OR (Star AND Med)) AND (VIVA OR "Combo" OR "RF System" OR "RF

Electrode") AND "thyroid nodule" AND benign. Results were selected for further evaluation if the publication described human clinical data (i.e., not in an animal or cadaver) and provided adequate information to identify use of the subject device (STARmed VIVA combo RF System) in the appropriate clinical procedure (ultrasound-guided RFA) and patient population (cytologically confirmed BTNs).

Summary of the studies used for final evidence synthesis. The SOTA review encompassed 31 publications, including society guidelines, systematic reviews, and meta-analyses, and showed that RFA has a similar effectiveness and lower rate of complications than surgery. Adverse event benchmark rates were compiled. Effectiveness outcome benchmarks were also compiled, including symptomatic score, cosmetic score, nodule volume, volume reduction ratio (VRR), and function normalization (for autonomously functioning nodules only). VRR at 6 months was considered the primary indicator of successful performance for non-functioning nodules. The subject device portion of the SLR encompassed 42 publications, and included prospective and retrospective cohort studies, randomized trials, and case series that described the use of the device in 20 or more patients, compiling the same adverse event and effectiveness outcomes as the SOTA review.

Findings. In terms of safety, the adverse event types and rates observed following treatment with the subject device were consistent with the adverse event results from the SOTA review, identifying no unique events or out of range rates for the subject device. In terms of effectiveness, all studies that used the subject device reported a VRR $\geq$ 50% at 6 months, regardless of geographic location, nodule composition, baseline nodule volume, or operator experience.

Conclusions. Key findings from the SLR have been incorporated into the Instructions for Use. The Instructions for Use include limitations regarding clinically supported electrode diameters, electrode lengths, exposed tip lengths, and RF power settings as identified in the SLR. The findings of the SLR support the proposed indications for use and do not raise new questions of safety or effectiveness compared with the predicate device, which has the same mechanism of action and substantially equivalent technological characteristics as the subject device. The SLR provides substantial evidence that the VIVA combo RF System demonstrates a reasonable assurance of safety and effectiveness for its intended purpose (i.e., RFA of BTNs in adults). Because the SLR provides a reasonable assurance of safety and effectiveness, additional clinical investigations are not necessary for establishing substantial equivalence.

11. Conclusion

The indications for use of the subject device have changed and, to support the indications for use, the intended user has been changed. However, the two devices have the same intended use: RF ablation. The electrodes are the same, except for the addition of a minor design variation, the VIVA RF Electrode V2-T, which is similar to VIVA RF Electrode V2. These differences are considered minor, do not raise any new questions of safety and effectiveness, and the data included in this submission demonstrate that these electrodes are

as safe and effective as the predicate electrodes. Thus, the subject device is substantially equivalent to the predicate device.