October 24, 2018

NeuWave Medical, Inc.
Dan Kosednar
Director of Regulatory Affairs and Quality Assurance
3529 Anderson Street
Madison, Wisconsin 53704

Re: K173756
  Trade/Device Name: Certus 140 2.45GHz Ablation System
  Regulation Number: 21 CFR 878.4400
  Regulation Name: Electrosurgical cutting and coagulation device and accessories
  Regulatory Class: Class II
  Product Code: NEY
  Dated: September 13, 2018
  Received: September 14, 2018

Dear Dan Kosednar:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Jennifer R. Stevenson -S3

For 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
Indications for Use

510(k) Number (if known)

K173756

Device Name

Certus 140 2.45 GHz Ablation System and Accessories

Indications for Use (Describe)

The NeuWave Medical Certus 140™ 2.45 GHz Ablation System and Accessories are indicated for the ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings, including the partial or complete ablation of non-resectable liver tumors.

The Certus 140™ 2.45 GHz Ablation System is not indicated for use in cardiac procedures.

The system is designed for facility use and should only be used under the orders of a clinician.

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.

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PRASStaff@fda.hhs.gov

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The 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

Predicate Devices
The Certus 140 2.45 GHz Ablation System and Accessories is substantially equivalent to the following currently marketed device:

- Primary Predicate - Certus 140 2.45 GHz Ablation System and Accessories – Class II – 21CFG878.4400 which has been the subject of a cleared 510(k) with the FDA log number K160936.
- Reference Device - Covidien Cool-Tip™ RF Generator System and Accessories, Class II – 21CFR878.4400 which has been subject of a cleared 510(k) with FDA log number K053290.

Indications for Use
The NeuWave Medical Certus 140™ 2.45 GHz Ablation System and Accessories are indicated for the ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings, including the partial or complete ablation of non-resectable liver tumors.

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The system is designed for facility use and should only be used under the orders of a clinician.
Comparison of Intended Use and Indications for Use

<table>
<thead>
<tr>
<th></th>
<th>Subject Device, K173756</th>
<th>Predicate Device, K160936</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intended Use</strong></td>
<td>To thermally ablate soft tissue using microwave energy.</td>
<td>To thermally ablate soft tissue using microwave energy.</td>
</tr>
<tr>
<td><strong>Indications for use</strong></td>
<td>The NeuWave Medical Certus 140™ 2.45 GHz Ablation System and Accessories are indicated for the ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings, including the partial or complete ablation of non-resectable liver tumors. The Certus 140™ 2.45 GHz Ablation System is not indicated for use in cardiac procedures. The system is designed for facility use and should only be used under the orders of a clinician.</td>
<td>The NeuWave Medical Certus 140™ 2.45 GHz Ablation System and Accessories are indicated for the ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings. The Certus 140™ 2.45 GHz Ablation System is not indicated for use in cardiac procedures. The system is designed for facility use and should only be used under the orders of a clinician.</td>
</tr>
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</table>

The subject and the predicate devices are similar in terms of technological characteristics as microwave devices used to ablate soft tissue. The subject device differs from the predicate device by a modification to the Indications for Use as shown in the above table and the associated changes to the labeling. The technological characteristics otherwise remain the same. To support that the change in indications for use does not change the intended use of the subject device when compared to the predicate device, the sponsor provided nonclinical bench, in-vivo animal testing and Real-World Evidence meta (clinical data from published peer-reviewed literature papers). Results of nonclinical testing and Real-World Evidence demonstrated the subject device has the same intended use as the predicate device.

**Device Description**

The system has a single 2.45 GHz signal source generator and three (3) independent power amplifiers, each capable of producing up to 140W each. One, easy to use, touch-screen user interface controls the system. The User Interface can be set for either Ablation Mode or Surgical Mode. An optional footswitch can be connected to the system to control power delivery in Surgical Mode. Up to three (3) energy delivery accessories can be connected to and powered by the system at one time. An intermediate junction box or Power Distribution Module (PDM) reduces system set up complexity.

A variety of sterile, single-patient use energy delivery accessories (ablation probes and surgical tools) are available for use with the Certus 140. All are comprised of a sharp trocar on the end of a cannula, a handle, a cable and a connector assembly.

Models Certus²⁻¹⁸ and Certus⁹⁸ ablation probes are available in either 17-gauge or 15-gauge cannulas and are available in 15 cm and 20 cm lengths. These probes have a cable length of 1.4m.

Models Certus¹⁶¹ ablation probes are available only in 17-gauge cannulas and are available in 15 cm and 20 cm lengths. These probes have a cable length of 1.4m.
The model Certus\textsuperscript{SR} ablation probe has a 13-gauge cannula and is available in a 25 cm length only. Certus\textsuperscript{SR} probes have a cable length of 1.4m.

### Ablation Probe Design Application Overview

<table>
<thead>
<tr>
<th></th>
<th>Percutaneous Ablation</th>
<th>Laparoscopic Ablation</th>
<th>Open Surgical Ablation</th>
<th>Open Surgical Coagulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certus\textsuperscript{LK}</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Certus\textsuperscript{LN}</td>
<td>X</td>
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<td>X</td>
<td></td>
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<tr>
<td>Certus\textsuperscript{PR}</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
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<tr>
<td>Certus\textsuperscript{SR}</td>
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</table>

Each energy delivery accessory contains temperature measurement sensors that help monitor performance and ensure patient and operator safety.

The antenna of the Certus\textsuperscript{PR} probe is designed to limit the length of the ablation for instances when a shorter ablation zone is desired. Certus\textsuperscript{PR} Probes were developed to provide physicians with an additional ablation probe designed specifically for creating smaller ablation zones than the Certus\textsuperscript{LK}, Certus\textsuperscript{LN} and Certus\textsuperscript{SR} probes. The Certus\textsuperscript{PR} probes are designed to produce ablations that encompass the tip of the probe while limiting the overall length of the ablation. Certus\textsuperscript{PR} probes will enable physicians to ablate smaller lesions while limiting necrosis of adjacent tissue when compared to other Certus probes.

The Certus\textsuperscript{SR} probes length and gauge size result in a probe for use in laparoscopic applications.

A CO\textsubscript{2} based cooling system ensures the non-active portion of the probe does not exceed temperature requirements. Additionally, the CO\textsubscript{2} enables the Tissu-Loc function, which can be used to adhere or stick the probe in place prior to starting ablation therapy.

The system uses two (2) E-sized CO\textsubscript{2} cylinders. When a tank in use empties, the system will automatically switch to using the other tank and notify the user to replace the empty tank.

An accessory, a small plastic probe clip that can hold two 17-gauge probes and allow the user to easily hold both while performing planar coagulation, is available.

Ablation Confirmation software (K171022) is available as an option on the Certus 140. When this option is supplied, a second monitor is provided with the system which hosts the Ablation Confirmation user interface.

**Modifications**

No significant design changes were made to the Certus 140 to support this 510(k). This 510(k) was submitted to update the Certus 140 indications for use to include the partial or complete ablation of non-resectable liver tumors.
## Comparison to Predicate

<table>
<thead>
<tr>
<th>Feature/Specification</th>
<th>Certus 140 with V3.0.X SW (K160396)</th>
<th>Certus 140 with V2.0.X SW (K160936)</th>
<th>Comments/impact on safety and effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Probe applications</strong></td>
<td>Percutaneous, open surgical and in conjunction with laparoscopic. The CertuSurg GT surgical tool is for open surgical procedures only.</td>
<td>Percutaneous, open surgical and in conjunction with laparoscopic. The CertuSurg GT surgical tool is for open surgical procedures only.</td>
<td>This 510(k) includes no modifications to the Certus probe applications.</td>
</tr>
<tr>
<td><strong>User Interface Modes</strong></td>
<td>Surgical and Ablation</td>
<td>Surgical and Ablation</td>
<td>No changes in this 510(k)</td>
</tr>
<tr>
<td><strong>Power Delivery Initiation Method</strong></td>
<td>User Interface or Footswitch (Footswitch available in Surgical Mode only) or Finger-Switch</td>
<td>User Interface or Footswitch (Footswitch available in Surgical Mode only) or Finger-Switch</td>
<td>No changes in this 510(k)</td>
</tr>
<tr>
<td><strong>Available Energy Delivery Accessories</strong></td>
<td>Certus(^{LK}), Certus(^{LN}), Certus(^{SR}), Certus(^{PR}) Probes and CertuSurg GT</td>
<td>Certus(^{LK}), Certus(^{LN}), Certus(^{SR}), Certus(^{PR}) Probes and CertuSurg GT</td>
<td>No new probe types in this 510(k)</td>
</tr>
<tr>
<td><strong>Probe dimensions</strong></td>
<td>Certus(^{LK}) and Certus(^{PR}) probes are available in 15 gauge or 17 gauge and available in 15 and 20cm lengths. Certus(^{LN}) probes are 17 gauge and available in 15 and 20cm lengths. Certus(^{SR}) probe is 13 gauge and available only in a 25cm length.</td>
<td>Certus(^{LK}) and Certus(^{PR}) probes are available in 15 gauge or 17 gauge and available in 15 and 20cm lengths. Certus(^{LN}) probes are 17 gauge and available in 15 and 20cm lengths. Certus(^{SR}) probe is 13 gauge and available only in a 25cm length.</td>
<td>No changes in this 510(k)</td>
</tr>
<tr>
<td><strong>Software Version</strong></td>
<td>V3.0.X software</td>
<td>V2.0.X software</td>
<td>No significant change to the system SW was made since the previous 510(k) clearance (K160936). Changes made had no impact on safety and effectiveness.</td>
</tr>
<tr>
<td>Feature/Specification</td>
<td>Certus 140 with V3.0.X SW</td>
<td>Certus 140 with V2.0.X SW (K160396)</td>
<td>Comments/impact on safety and effectiveness</td>
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<td>impact on energy delivery, temperature measurement, CO2 cooling control or other risk mitigations or essential performance. All changes were made to address minor anomalies or make minor improvements to the user experience. Additionally, several changes were made to support CO2 tank configurations different from those sold in the US. These changes do not impact the function of US configured units.</td>
</tr>
<tr>
<td>Generator Output Power</td>
<td>Certus&lt;sup&gt;LK&lt;/sup&gt;, Certus&lt;sup&gt;LN&lt;/sup&gt; and Certus&lt;sup&gt;SR&lt;/sup&gt; Probes are limited to 140W for a single probe, 95W if 2 probes are selected and 65W if 3 probes are selected. Certus&lt;sup&gt;PR&lt;/sup&gt; Probes Maximum of 65W per probe regardless of the number of probes when used in Ablation Mode. In Surgical Mode, the maximum power for Certus&lt;sup&gt;PR&lt;/sup&gt; probes is 95W if 1 or 2 probes are used and 65W if 3 probes are used.</td>
<td>Certus&lt;sup&gt;LK&lt;/sup&gt;, Certus&lt;sup&gt;LN&lt;/sup&gt; and Certus&lt;sup&gt;SR&lt;/sup&gt; Probes are limited to 140W for a single probe, 95W if 2 probes are selected and 65W if 3 probes are selected. Certus&lt;sup&gt;PR&lt;/sup&gt; Probes Maximum of 65W per probe regardless of the number of probes when used in Ablation Mode. In Surgical Mode, the maximum power for Certus&lt;sup&gt;PR&lt;/sup&gt; probes is 95W if 1 or 2 probes are used and 65W if 3 probes are used.</td>
<td>No changes in this 510(k)</td>
</tr>
<tr>
<td>Antenna Design</td>
<td>Triaxial Antenna for Certus&lt;sup&gt;LK&lt;/sup&gt;, Certus&lt;sup&gt;LN&lt;/sup&gt; and Certus&lt;sup&gt;SR&lt;/sup&gt;</td>
<td>Triaxial Antenna for Certus&lt;sup&gt;LK&lt;/sup&gt;, Certus&lt;sup&gt;LN&lt;/sup&gt; and Certus&lt;sup&gt;SR&lt;/sup&gt;</td>
<td>No changes to the antenna design in this 510(k).</td>
</tr>
</tbody>
</table>
### Sterilization:

Certus 140 Microwave Ablation Probes are provided to customers sterile. The probes are packed in thermoform plastic trays containing a single probe and sealed with a Tyvek lid prior to sterilization. The product is over-packed in an e-flute box to further protect the sterile barrier.

The validated sterilization method for Certus 140 ablation probes is Ethylene Oxide. Device specific methods were developed using the “overkill” approach and validated per ISO 11135:2014. Results demonstrated a Sterility Assurance Level (SAL) of $10^{-6}$.

Testing conducted determined the worst case residual Ethylene Oxide (EO) level and the residual Ethylene Chlorohydrin (ECH) level to be below the FDA recognized limits of AAMI/ANSI/ISO 10993-7.

### Shelf Life:

Accelerated aging tests were conducted to confirm the validity of the 48-month shelf life.

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<table>
<thead>
<tr>
<th>Feature/Specification</th>
<th>Certus 140 with V3.0.X SW</th>
<th>Certus 140 with V2.0.X SW (K160396)</th>
<th>Comments/impact on safety and effectiveness</th>
</tr>
</thead>
</table>
| **Power**             | 20-95 (5 W increments) for Certus™ probes (65 W max in Ablation Mode)  
                        | 20-140 (5 W increments) for Certus™, Certus™ and Certus™ probes         | This aspect of probe design has not been modified from the predicate device. |
| **Target Ablation Time** | Up to 10 Min as limited by software. User may ablate for additional time after 10 minutes of ablation is complete. | Up to 10 Min as limited by software. User may ablate for additional time after 10 minutes of ablation is complete. | This aspect of probe design has not been modified from the predicate device. |
| **Planar Coagulation Time** | 5 seconds – 1 Minute | 5 seconds – 1 Minute | This aspect of probe design has not been modified from the predicate device. |
| **Monitored Parameters** |                           |                                      | No changes in this 510(k). |
| **Accessories**       | Dual Probe Clip  
                        | CT Table Mounting Adapter for PDM  
                        | Surgical Table Mounting Adapter for PDM  
                        | Foot switch (Locking USB or Standard USB) | Dual Probe Clip  
                        | CT Table Mounting Adapter for PDM  
                        | Surgical Table Mounting Adapter for PDM  
                        | Foot switch (Locking USB or Standard USB) |
**Biocompatibility:**
The Certus Microwave Ablation Probes are classified as an External Communicating Device, Tissue/bone/dentin patient contact, with a contact duration of (<24) hours. Based on this categorization, per Table A.1 of Annex A of ISO 10993-1, Cytotoxicity, Sensitization, and Irritation tests were performed. The results of all testing demonstrated that the Ablation Probes are biocompatible.

**Standards Testing**
The Certus 140 2.45 GHz Ablation System and Accessories has been designed to comply with the applicable portions of various International Standards, including:

- IEC60601-1:2005
- IEC60601-2-2:2006
- IEC60601-2-6:2012
- IEC60601-1-2:2014
- EN ISO 11607-1:2009
- ISO 10993-1: 2009

The Certus 140 2.45 GHz Ablation System and Accessories and the predicate device are substantially equivalent in design concepts, technologies and materials. The Certus 140 Ablation 2.45 GHz System and Accessories has been verified through testing that supports the compliance of Certus 140 2.45 GHz Ablation System and Accessories to the standards listed above.

**Performance Data**

**Nonclinical Testing**
Verification and validation testing were completed in accordance with the company's Design Control process in compliance with 21 CFR Part 820.30, which included testing that fulfills the requirements of FDA "Guidance on Software Contained in Medical Devices". Potential risks were analyzed and satisfactorily mitigated in the device design.

Nonclinical acute in-vivo (porcine) studies were conducted to compare the technological performance of the Certus 140 2.45 GHz Ablation System and Accessories to the reference device (K053290 Cool-Tip™). Ablation zone sizes and histological results were analyzed and evaluated.

**Real World Evidence (RWE) Meta-analysis**
The RWE was used to supplement the nonclinical performance testing (e.g., animal study) to conclude that the subject device can access and ablate liver tumors in open surgical, percutaneous and laparoscopic settings.

A review of peer-reviewed articles involving the use of the Certus 140 2.45 GHz Ablation System demonstrate microwave ablation technique efficacy (effectiveness) of the device for the ablation of non-resectable liver tumors.

A systematic review of literature and meta-analysis was conducted to compare the technique efficacy (effectiveness) of microwave ablation to radiofrequency ablation for the treatment of liver tumors. This meta-analysis included both randomized and observational studies. Technique efficacy
(effectiveness) is demonstrated by clinical follow up during which imaging is performed to ascertain complete ablation of tumor including an ablative margin. Technique efficacy (effectiveness) was used to confirm that the subject devices could reliably access liver tumors in percutaneous and laparoscopic settings.

**Search Strategy:**
The search strategy used three databases which are well-recognized as publication sources for systematic literature reviews. A systematic search of MEDLINE, EMBASE, and the Cochrane Central Register of Controlled Trials (CENTRAL) was conducted for relevant systematic reviews, randomized controlled trials (RCTs), and observational studies (prospective or retrospective cohort and case-control studies) using a search that involved controlled vocabulary and keywords related to our research question (e.g., “Liver Neoplasms”, “Microwave”, “Ablation Techniques”).

**Study Selection:**
Specific inclusion criteria were defined according to PICOS (i.e., population, intervention, comparator, outcomes, and study design). Studies were considered for inclusion in the meta-analysis if they were RCTs or observational studies comparing MWA with RFA in adults (≥18 years) with confirmed HCC or liver metastasis who either refused or were ineligible for surgery. Records were evaluated for eligibility by two independent reviewers and discrepancies were resolved either through consensus, or by adjudication from a third reviewer.

**Data Extraction:**
The sponsor indicates that the baseline characteristics and outcomes from the included studies were extracted using a standardized data extraction form developed in Microsoft Excel. The following study details were retrieved: study authors, publication year, study time frame, study design, country of origin, sample size, key patient characteristics (e.g., age, diagnosis, average tumor size, average number of ablated tumors, and duration of follow-up, etc.), intervention and comparator details [e.g., microwave system, frequency, utilization of trans arterial chemoembolization (TACE), etc.], and detailed outcomes data. If studies did not report the number at risk at each time point, the denominator for number treated was assumed to be the initial sample size. Data were extracted by one reviewer and then cross-checked for accuracy and completeness by a second reviewer.

**Study Outcomes**
The outcome of interest was technique efficacy (effectiveness) (defined as complete tumor ablation or complete response), measured at one week to three months post ablation.

**Risk of Bias Assessment**
Risk of bias assessment is acceptable because well-recognized risk of bias methodologies was used. The quality of studies included in the meta-analysis was assessed using the Cochrane Risk of Bias (RoB) tool for RCTs and the Newcastle–Ottawa quality assessment Scale (NOS) for observational studies.

**Data Synthesis and Statistical Methods**
The DerSimonian–Laird random-effects model was used for the meta-analysis and a forest plot was generated. The relative risk (RR) and the corresponding 95% CI were calculated. All analyses were conducted for RCTs alone, observational studies alone, and the combination of RCTs and observational studies.
An $I^2$ value was generated to describe the percentage of variance attributable to heterogeneity among studies. Regardless of the observed statistical heterogeneity, the following sub-group analyses were conducted if there were at least two studies informing each subgroup: 1) tumor size (<2.5 versus >2.5 cm); 2) type of liver tumor (HCC versus metastasis); 3) impact of adding another treatment to both arms (MWA and RFA versus MWA+TACE and RFA+TACE); 4) MWA frequency (915 versus 2450 MHz); and 5) microwave ablation system (NeuWave versus non-NeuWave). Additionally, several sensitivity analyses were performed to assess the impact of alternative methods (i.e., fixed effects model) and study quality (i.e., exclusion of lower quality studies, defined as any RCT with high risk for any domain of the RoB tool or any observational study with ≤7 stars on the NOS). Publication bias was examined using funnel plots. Data were analyzed using STATA (Version 15.1, Texas, USA).

**Results**

A total of 1,379 citations were identified from database searching. After screening, eighteen studies consisting of a total of 1,924 patients were included in the meta-analysis. Fifteen studies used a percutaneous approach for ablation and three studies used a laparoscopic approach. A PRISM Flow Diagram to visualize the RWE evaluation procedure (i.e., Identification, Screening, Eligibility, and Included Studies) was utilized.

The nonclinical data and Real-World Evidence demonstrate that Certus 140 microwave ablation system and probes can reach target tumors in the liver using the open, percutaneous and laparoscopic tissue access methods.

**Conclusion**

The subject device differs from the predicate device by modification to the Indications for Use and the associated changes to the labeling. The change in the indications for use does not result into a new intended use, and, hence, the intended use is substantially equivalent to the intended use of the predicate device as demonstrated by nonclinical bench, in-vivo animal testing and Real-World Evidence meta-analysis. There are minor differences in technological characteristics, but they do not impact the essential performance of the subject device system and accessories. Hence, the subject device is substantially equivalent to the predicate device.