March 24, 2023

Sprig Oral Health Technologies, Inc.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K230797
Trade/Device Name: SmartMTA Capsule
Regulation Number: 21 CFR 872.3820
Regulation Name: Root canal filling resin
Regulatory Class: Class II
Product Code: KIF
Dated: March 22, 2023
Received: March 22, 2023

Dear Prithul Bom:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K230797

Device Name
SmartMTA Capsule

Indications for Use *(Describe)*
The SmartMTA Capsule is indicated for use as:

- Orthograde root canal filling material
- Repair of root perforations during root canal therapy (endodontic therapy), or as a consequence of internal and external resorption.
- Repair of root canals as an apical plug during apexification
- Root end filling
- Pulp capping
- Pulpotomy/Partial Pulpotomy

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

K230797

**Section 5: 510 K Summary**

**1. Application Information:**

**Date Prepared:** February 10, 2023

**Company Name:** Sprig Oral Health Technologies, Inc.

**Address:** 6140 Horseshoe Bar Road, Suite L, LOOMIS, CA 95650

**Contact:** Ricky Quintana

**Designation:** Director of Operations

**Email:** ricky@sprigusa.com

**Phone #:** 1-916-542-4545

**Fax #: N/A**

**List of devices for which clearance is requested:**

SmartMTA Capsule (common Name: root filling material)

**2. <u>Name of the Device:</u>**

**Trade name:** SmartMTA Capsule (common name: root filling material)

**Device Type:** Root Canal Filling material

**Regulation Description:** Root Canal Filling Resin

**Review Panel:** Dental

**Regulation Number:** 21 CFR 872.3820

**Device class:** Class II

**Product Code:** KIF

**3. Predicate Device Information:**

The legally marketed devices to which substantial equivalence is being claimed are:

**Table 5A – Predicate Devices**

**Device Manufacturer 510K number**

| Device | Manufacturer | 510 K # |
|---|---|---|
| RetroMTA-<br>OrthoMTA II | BioMTA | K132825 |

**4. Device Description:**

The major compositions of the SmartMTA Capsule are Calcium Carbonate ($CaCO_3$), Silicon Dioxide ($SiO_2$), Aluminum Oxide ($Al_2O_3$), Zirconium Oxide ($ZrO_2$) and Distilled water and it has been showing good sealing ability and biocompatibility. It is prepared as a mixture of powder and water and is used in a putty form which gradually hardens in the oral environment.

SmartMTA Capsule is ideal for orthograde root canal filling. SmartMTA Capsule is compositionally formulated to have the physical properties, setting requirements and characteristics necessary for a clinically effective root canal filling material.

**5. Device Configuration:**

| | |
|---|---|
| SmartMTA Capsule | Capsule: 20 ea.<br>- Portland cement powder: 4g (0.2g cap x 20 ea.),<br>- Solution: 2.8cc (0.14cc x 20 ea.)<br>-IFU |
| SmartMTA Capsule | Capsule: 10ea<br>- Portland cement Powder: 2g (0.2g cap x 10 ea.),<br>- Solution: 1.4cc (0.14cc x 10 ea.)<br>-IFU |

**6. Device Composition:**

| Trade Name | Materials | Weight (%) |
|---|---|---|
| Portland Cement (powder form) | Calcium Carbonate ($CaCO_3$) | 61.0 |
| | Silicon Dioxide ($SiO_2$) | 11.7 |
| | Aluminum Oxide ($Al_2O_3$) | 2.3 |
| | Zirconium Oxide ($ZrO_2$) | 25 |
| Total | - | 100 |
| Distilled Water | Distilled water | 0.14cc |

**7. Indications for Use:**

SmartMTA Capsule root repair materials is indicated for use as

- An orthograde root canal filling material

- Repair of root perforations during root canal therapy (endodontic therapy), or as a consequence of internal and external resorption.

- Repair of root canals as an apical plug during apexification

- Root end filling

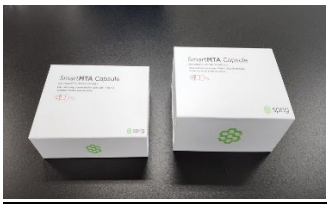
- Pulp capping

- Pulpotomy/Partial Pulpotomy

**8. Substantial Equivalence:**

SmartMTA Capsule has exactly the same physical and biocompatible properties and demonstrates comparable performance specifications to RetroMTA-OrthoMTA II Material. In addition, SmartMTA Capsule has a comparable delivery system to RetroMTA-OrthoMTA II Material. The bench and biocompatibility testing performed on the candidate and predicate device demonstrate that any differences in their technological characteristics do not raise any new questions as to safety and effectiveness. Therefore, it is concluded that SmartMTA Capsule is safe, effective, and is substantially equivalent to the predicate device.

| Item | Candidate Device | Predicate Device | Equivalence comparisons |
|---|---|---|---|
| Device Name | SmartMTA Capsule | RetroMTA-OrthoMTA II | - |
| Manufacturer | BioMTA | BioMTA | Same as predicate |
| 510(K) Number | - | K132825 | - |
| Device Classification Name | Root filling material | Root filling Material | Same classification as predicate |
| Regulation Number | 872.3820 | 872.3820 | Same Regulation # as predicate |

| | | | |
|---|---|---|---|
| Product Code | KIF | KIF | Same Product code as predicate |
| Regulatory Class | Class II | Class II | Same class II as predicate |
| Patient population | Adult and Pediatric | Adult and Pediatric | Same as predicate |
| Device description | The major compositions of the SmartMTA Capsule are Calcium Carbonate ($CaCO_3$), Silicon Dioxide ($SiO_2$), Aluminum Oxide ($Al_2O_3$), Zirconium Oxide ($ZrO_2$) and Distilled water, and it has been showing good sealing ability and biocompatibility. It is prepared as a mixture of powder and water and is used in a putty form which gradually hardens in the oral environment. SmartMTA Capsule is ideal for orthograde root canal filling. SmartMTA Capsule is compositionally formulated to have the physical properties, setting requirements and characteristics necessary for a clinically effective root canal filling material. | The major compositions of the RetroMTA-OrthoMTA II are Calcium Carbonate ($CaCO_3$), Silicon Dioxide ($SiO_2$), Aluminum Oxide ($Al2O_3$), Zirconium Oxide ($ZrO_2$) and Distilled water, and it has been showing good sealing ability and biocompatibility. It is prepared as a mixture of powder and water and is used in a putty form which gradually hardens in the oral environment. RetroMTA-OrthoMTA II is ideal for orthograde root canal filling. It is compositionally formulated to have the physical properties, setting requirements and characteristics necessary for a clinically effective root canal filling material. | Same as formula as the predicate, except our device does not require hand mixing. |
| Device Photo and content |  <br>  |  <br>detailed content:<br>  | Predicate: Powder form contained in a aluminum fail packet,<br><br>SmartMTA Capsule: Powder form contained in chamber 2 inside the capsule and distilled |

| | | | |
|---|---|---|---|
| |  <br><br>detailed content:<br><br>1) Inner Body<br>2) Tip<br>3) Outer body<br>4) Red Plunger<br><br>Punch bottom at the time of use to puncture the foil barrier allowing the mixing of cement and water just before use. | 1) Mixing tray<br>2) Distilled water<br>3) Portland cement powder in plastic vial within aluminum foil packet | water in chamber 1 |
| Outer container material (primary packaging) | Capsule:<br><br>1) Inner Body: (CAS # 9002-88-4 (Low density Polyethylene)<br>2) Tip: CAS # 9010-79-1(1-propene, polymer with ethene)<br>3) Outer body: (Marlex 9708 HDPE)<br>4) Red Plunger: (CAPILENE T 50) | Aluminum foil, Plastic vials | Primary Packaging is a bit different from the predicate, however the primary packaging material used for the candidate device are safe (see SDS attached in this submission) |
| Indications for Use | • Orthograde root canal filling material<br><br>• Repair of root perforations during root canal therapy (endodontic therapy), or as a consequence of internal and external resorption.<br><br>• Repair of root canals as an apical plug during | • Orthograde root canal filling material<br><br>• Repair of root perforations during root canal therapy (endodontic therapy), or as a consequence of internal and external resorption.<br><br>• Repair of root canals as an apical plug during apexification | Same as predicate<br><br>(Predicate device: hand mix)<br><br>(Our device: auto Mix) |

<table>
<tr><td></td><td>apexification<br><br>• Root end filling<br><br>• Pulp capping<br><br>• Pulpotomy/Partial Pulpotomy</td><td>• Root end filling<br><br>• Pulp capping</td><td></td></tr>
<tr><td>Similar Physical Properties</td><td>Same material used, only different ratio Powder / water<br>200/140 or 1 to 0.7<br>Capsule auto mix<br>(Consistent mix)</td><td>Same material used, only different ratio Powder / water varying from:<br>-1 to 0.3<br>-1 to 0.5<br>Upon hand mixing (variable mix consistency).</td><td>Same as predicate<br>See comments on Device differences section below this comparison table</td></tr>
<tr><td>Biocompatibility</td><td>Biocompatible<br><br>(The fact that the powder cement and water are contained in the capsule does not alter biocompatibility testing. The raw materials for primary packaging are safe)</td><td>Biocompatible</td><td>Same as predicate (same raw material and formula) only different packaging<br><br>SDS of packaging material (including capsule)</td></tr>
<tr><td>Sterilization</td><td>Non-sterile</td><td>Non-sterile</td><td>Same as predicate</td></tr>
<tr><td>Chemical Components</td><td><table><tr><td>Materials</td><td>Weight (%)</td></tr><tr><td>Portland Cement</td><td>75</td></tr><tr><td>$ZrO_2$</td><td>25</td></tr><tr><td>Distilled water</td><td>0.14cc</td></tr></table>Powder/water ratio: 1 to 0.7</td><td><table><tr><td>Materials</td><td>Weight (%)</td></tr><tr><td>Portland Cement</td><td>75</td></tr><tr><td>$ZrO_2$</td><td>25</td></tr><tr><td>Distilled water</td><td>Tube of 0.15g</td></tr></table>Powder/water ratio: 1 to 0.3, 1 to 0.5</td><td>Same as predicate (same ingredients)<br><br>Different Powder / water ratio</td></tr>
</table>

| | | | |
|---|---|---|---|
| Shelf life | 2 years | 3 years | Similar to predicate device |

**9. Similarities and differences:**

**Summary of Technical Characteristics:**

The clinical, technical, and biological characteristics of our device and the predicate device are exactly the same. Same recipe of the predicate device, same manufacturer. Only the way the cement and water are packaged and the mixing at the time of use are different.

**Device differences:**

The only 2 differences between our device and the predicate are the Capsule (primary packaging (predetermined amount of powder and predetermined amount of water contained in the capsule)) instead of using a tray to mix an amount of powder (contained in an aluminum foil packet) with estimated amount of water hand mix (contained in 2 small bottles/vials) to consistency for use).
And the difference in Powder / water ratio (1 to 0.7 for our device, 1 to 0.3 / 1 to 0.5 for predicate).

This difference in fact assures a consistent powder/water ratio each time, compared to an inconsistent hand mix powder water on a tray prior to use (like the predicate).

The same formula is used and due to its hydrophilic nature, the difference of powder/ water ratio does not bring an additional risk or level of concerns for the safe and effective use of our device.

Additionally, the primary packaging (SmartMTA Capsule) materials used are known plastics (frequently used in the food and medical device industries) which do not alter the powder / water content in the capsule (see Cytotoxicity test done on FFF of our device SmartMTA Capsule).

For detailed assessment of the candidate and predicate device differences see Section 12 “Substantial Equivalence Discussion” of this 510K submission.

**10. Discussion of Clinical Test Performed:**

There was no clinical testing required to support the medical device as the indications for use are equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device.
The Biological Safety Evaluation report done on the predicate device (Ref BSE-2021-19) demonstrates that the composition of the cement/water is biologically safe and effective. The SmartMTA Capsule uses exactly the same cement composition with a predetermined cement / water ratio (200mg/140); therefore we are confident of the safety and effectiveness of SmartMTA Capsule.

In addition, the safe clinical use historical data from RetroMTA also demonstrates the safety and effectiveness of the cement / water composition.
The following complaint data from Year 2018 to June 2022 confirms the safety:
# of RetroMTA sold units vs # of complaints:

-Small "SmartMTA "(private label) / "Retro MTA" (BioMTA): 930 units (x 10 vials) = 9,300 vials: no complaint to date.

-Large "SmartMTA "(private label) / "Retro MTA" (BioMTA): 633 units (x 50 vials) = 31,650 vials: no complaint to date.

-The FDA MAUDE data base was also reviewed for RetroMTA (product code KIF) and similar MTA devices Product Code KIF,
-For 2022, 0 to date No MTA type sealant issue reported
-For 2021, 1 reportable event where the MTA did not properly set causing pain to the patient, the tooth was eventually extracted.
-For 2020, 0 reportable event
-For 2019, 0 reportable event
-For 2018, 0 reportable event
-For 2017, 0 reportable event

In addition, the verification and validation testing of the device was found to be acceptable and supports the claims of substantial equivalence.

**11. Discussion of Non-clinical Tests Performed for determination of Substantial Equivalence:**

The bench test provided substantial information and validation of the appropriate mixing ratio to meet the expectations of pediatric dentists for their specific use. Repackaging the SmartMTA product into a triturable, auto-mix capsule form will help make the mixing of the material faster, provide a predictable mix consistency no matter the experience/skill of the assistant, and will provide an alternative method by allowing the MTA material to be directly applied to the pulp chamber without contact to any other surfaces or instruments in the dental operatory compared to the predicate device "hand mix" material. This technique also reduces the risk of cross contamination, as the

individually sealed, prefilled capsule reduces the amount of contact with the product prior to placement into the tooth. By the ability to apply directly from the tip of the capsule, virtually no opportunity is given to contaminate the product prior to use. These benefits were validated by the overwhelmingly positive responses from the sampled end-user dentists.

Additional testing data and correlation with ISO 6876:2012:

ISO 6876:2012 is a specific standard, that by definition, relates to root canal sealing materials. And while this is true of the use of root canal sealers, of which MTA can be used, the candidate is specifically designed for use in the pulp chamber of the tooth and not in the actual tooth's root canal system as specified in the standard. A root canal of a tooth is a long and narrow passage that leads from the pulp chamber to the apex of the tooth and exits out the end, or tips of the roots. In a three rooted tooth you would expect to have one pulp chamber and three canals, likewise in a two rooted tooth you would expect to have one pulp chamber and two root canals, although this is not always a set rule. It is therefore very important to have a specific consistency and thickness of material when used in this small, confined space. The candidate is to be used in the pulp chamber of the tooth only and is not intended to be used down inside the root canal system. This makes the specifications for thickness and working time less important, as the dentist is much more interested in the ability to "pack" the material or to condense it into the pulp chamber. In essence, the candidate is used to cover over the root canal system and seal it from the outside. As noted in the standards introduction, Section 1 (scope) the standard only includes orthograde use, not retrograde. Our intended use is similar to a retrograde application because it is not intended to be used within the root canal system of the tooth. Because of this difference, the dentist prefers the material to be as thick as possible to be able to mold/condense/shape the material in the preparation. He/she would then place a base material over the candidate and continue to restore the tooth with restorative composite or a stainless steel or zirconia crown. The intent of the candidate is to seal the outside of the root canal system to prevent bacteria from entering the internal root canal system of the tooth. The candidate is designed to be able to set in the presence of moisture. As with concrete (a very similar material), the ability for the candidate to set slower actually makes for a stronger finished product. This would not be the case with a sealer that was intended to be used within the root canal system of the tooth. We are talking about two very different applications, and in the authors professional opinion, the ISO 6876 standard is specifically designed for a material that will be used within the root canal system of a tooth, a location and use for which the candidate is not intended.

ISO 6876:2012 data testing:
The difference in thickness and consistency is due to the difference in the mixing ratio of water / cement:
The preconized ratios are the following for the candidate and the predicate devices:
-RetroMTA is 1:0.3 / 1 to 0.5=powder: water,
-SmartMTA Capsule is different due to 1:0.7=powder: water.

The following test data was gathered according to the ISO 6876:2012 testing for the candidate and predicate devices: see summary table below:

| Test | criteria | Candidate device 200/160 | Candidate device 200/140 | RetroMTA |
|---|---|---|---|---|
| Flow: | >17mm | | 9.375 mm | not tested |
| Working time: | ≤30min | 20 minutes | not tested | not tested |
| Setting time: | 3hr30min ±10% | 3h35 minutes | 60 minutes | 2 minutes 30 s to 27 minutes |
| Film thickness: | ≤50μm | 43μm | not tested | not tested |
| Solubility | < 3% | 1.92% | < 3% | 1.4% |
| Radiopacity fulfilled: | ≥3.0mm | 4.4 mm | 4.33 mm | 5.0 mm |

As defined in the testing data from the Candidate and predicate device the ISO 6876:2012 was used and followed for most parts.
However, some of the testing recommended by the standard were either not executed / undertaken / measurable according to the standard or fell outside the acceptable / recognize test results range such as the Flow, working time, film thickness for the 200/140 ratio of subject device and predicate device.

The flow, working time and film thickness are not critical for the safety and effectiveness of this sealing material due to the fact that it is a hydrophilic material going into the patient cavity (humid environment (body fluid such as blood, saliva…, which will maintain a humid environment until full setting of material which could take up to 24 hours, and doing so assuring a stronger bound).

Those set of variables flow, working time and film thickness are dependent of and in correlation with the amount / ratio of powder and distilled water added prior to use and the dentist preparing the mixing (adding more or less water to the powder according to the dentist's preferred consistency and human factor not reproducing the exactly the same mixing ratio each time, therefore entering an additional variable and in fact a variable range of powder / water ratio.
The human factor, dentist assistant or dentist himself, is not able to repeatedly assure the same mixing powder water ratio. This does not affect the intended use of the root canal sealing material as discussed above due to its hydrophilic nature. This is also confirmed by the safe and historical clinical use of the predicate device already on the market.

The working time (allowing the material to be handled without hardening too much) depends on the amount of water mixed with the powder, therefore a waterier mixing will allow a bit more time to work with. For the predicate device these tests were not measurable with the manufacturer IFU's since it falls outside the established range from the standard ISO 6876 for overall root canal filling materials.

For the candidate device (SmartMTA Capsule) the flow test results showed to be outside

the established standard range for the test done on the 200/140 ratio but do fall in the established range for the 200/160 ratio on first battery of test. For the same reason defined above for the predicate device, this does not constitute a concern according to the intended use of the device.
For the same reason the Working time and Film thickness were not conducted either since they are not measurable according to the standard set ranges.

However, the fact that flow, working time and film thickness were not tested and or not measurable according to the ISO 6876:2012 for the 200/140 ratio does not raise additional risk, the predicate device has been used on the market for several years with the same formula and distilled water (variable ratio according to amount of powder and water mixed by dentist upon use)

In addition, Biocompatibility testing (cytotoxicity) has been performed on the candidate device (see Biocompatibility section 15 of this submission, and biocompatibility data from predicate and candidate device confirming it is safe for use).
Although the difference in the ratio of water to be mixed, and of the primary packaging, there is no difference in biocompatibility.

A biological evaluation was also conducted on the predicate device and confirms the safe clinical use of this formulation.

Shelf life: Tested for the ratio 200/140 and for ratio 200/160 and determined to be 2 years.

This difference in fact assures a consistent powder/water ratio each time with the correct consistency for the device's intended use. Therefore, as discussed above, those differences do not bring an additional risk or level of concern for the safe and effective use of our device. The device still has the same characteristics in terms of material (Exact same formulation) and indications for use of the cleared predicate device.

In addition, this bench top test allowed us to find the ratio that would be thick enough to support the needs of the dentist while still making sure that the capsule would function as designed and not clog or malfunction in dispensing the material properly.

The ability to provide the market with an individually packaged, triturable auto-mix MTA capsule will not only make the process of using MTA in the pediatric dental office easier, faster, and produce a more predictable mixture no matter what assistant the dentist is using that particular day but will also reduce the risk of cross contamination. These benefits, validated by the participating dentist, stand to make this new product a valuable tool for pediatric dentists striving to provide the best care possible for their little patients.

## 12. Conclusions:

The Sprig Oral Health Technologies, Inc. SmartMTA Capsule is substantially equivalent in terms of performance, indications for use, and biocompatibility to the cleared and marketed predicate devices RetroMTA-OrthoMTA II (K132825). Any technological

differences between the SmartMTA Capsule and the predicate device do not raise any questions regarding the safety and effectiveness of the subject device (as defined in detailed in section 12 “Substantial Equivalence Discussion” of this 510K submission).

The information provided in this submission supports the substantial equivalence to the predicate device and that the system is safe and effective for the users/operators.

The conclusions drawn from the nonclinical and clinical tests demonstrate that the SmartMTA Capsule is as safe, as effective, and performs as well as or better than the legally marketed device identified.