June 7, 2019

Engineered Endodontics
% John Ziobro
Principal Consultant
SpectraMedEx, LLC
3215 Golf Road #1459
Delafield, Wisconsin 53018

Re: K182145
Trade/Device Name: tün® ultrasonic tips product family
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC
Dated: April 24, 2019
Received: May 1, 2019

Dear John Ziobro:

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,

for Malvina B Eydelman, M.D.
Director
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K182145

Device Name
tün® ultrasonic tips product family

Indications for Use *(Describe)*

tün® ultrasonic tips are intended for use by dental professionals for the removal of soft and hard tissue during endodontic root canal preparation procedures. They can also aid in the removal of endodontic posts and other intra-canal blockages.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# K182145 Traditional 510(k) Summary

1. Summary Date: June 1, 2018

2. Applicant Name: Engineered Endodontics, LLC
W134 N4965 Campbell Drive
Menomonee Falls, WI 53051
Establishment Registration Number: 3012322979

3. Submission Correspondent: On behalf of Engineered Endodontics, the following consultant is assigned the responsibility of submission correspondence:
John F. Ziobro, Principal Consultant
SpectraMedEx, LLC
3215 Golf Road, #149
Delafield, WI 53018
Ph: 262.719.8922

4. Trade Name: tün® ultrasonic tips product family

5. Common Name: Scaler, Ultrasonic

6. Description:
tün® ultrasonic tips are an accessory to a piezoelectric ultrasonic handpiece and scaler unit. The tün® ultrasonic tips are made from 17-4ph Stainless Steel. Alloy 17-4ph (UNS S17400), Type 630, is a chromium-nickel-copper precipitation-hardening martensitic stainless steel with an addition of niobium. The tips will be available in M3xO.5 and M3x0.6 thread with 6 different tip designs. 1 tip design is devised for post removal; the remaining 5 tips are designed for negotiating the various angles and directions of root canals. Certain models have diamond (zirconium nitride) coating.

7. Manufacturing Site: Engineered Endodontics, LLC
W134 N4965 Campbell Drive
Menomonee Falls, WI 53051
Establishment Registration Number: 3012322979

8. Classification Regulation, Class, Product Code, Description & Panel:

| Regulation # | Class | ProCode | Description | Panel |
|---|---|---|---|---|
| 21CFR872.4850 | II | ELC | Scaler, Ultrasonic | Dental |

9. Predicate Device(s): Predicate:
510(k) Number: K132609
Manufacturer: ESSENTIAL DENTAL SYSTEMS, INC.
89 Leuning Street, Suite 8
South Hackensack, NJ 07606
Trade Name: EDS ULTRASONIC TIPS
Classification Regulation, Class, Product Code, Description & Panel:

| Regulation # | Class | ProCode | Description | Panel |
|---|---|---|---|---|
| 21CFR872.4850 | II | ELC | Scaler, Ultrasonic | Dental |

10. Proposed Indication for Use:
    tün® ultrasonic tips are intended for use by dental professionals for the removal of soft and hard tissue during endodontic root canal preparation procedures. They can also aid in the removal of endodontic posts and other intra-canal blockages.

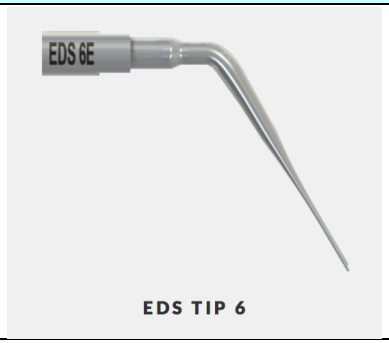
11. Compliance to Special Controls / Performance Standards: Compliance to the following recognized consensus standards is declared:
    - ISO 7405 Second edition 2008-12-15 *Dentistry - Evaluation of biocompatibility of medical devices used in dentistry* [Including: Amendment 1 (2013)]. The application of this standard resulting in testing to:
      - ISO 10993-5:2009 / (R) 2014 *Biological Evaluation of Medical Devices-Part 5: Tests for in vitro cytotoxicity*
      - ISO 10993-10:2009 / (R) 2014 *Biological Evaluation of Medical Devices-Part 10: Tests for irritation and skin sensitization*
    - ISTA 3A *General Simulation Performance Test Procedure: Packaged- Products for Parcel Delivery System Shipment 150lbs or less*

12. Technological Characteristics
    The proposed device is similar to the predicate device and as such it has substantially equivalent technological characteristics.

13. Comparison to Predicates
    The main differences between the tün® ultrasonic tips under review and the predicate device cleared under K132609 are as follows:
    - The proposed device is plated while the predicate device is not. This difference is a function of the manufacturing method and does not affect the overall safety or performance of the device. Note: The predicate device chosen by EDS that cleared under K960889 used Titanium Nitride and Zirconium Nitride as plating materials.
    - The proposed device is manufactured by sintering while the predicate device is machined. The end result from either method are ultrasonic tips with similar geometries and identical intended uses. The different manufacturing methods simply reflect the in-house equipment / manufacturing capabilities of the two different companies and do not affect the overall safety or performance of the device.
    - The proposed device uses a Chromium:Nickel:Copper stainless steel alloy, while the predicate device uses a Chromium:Nickel:Molybdenum stainless steel. The materials were chosen based on the manufacturing methods and do not affect the overall safety or performance of the device.
    - The proposed device offers 6 variants; the predicate device offers 6 variants, but there isn't an exact 1:1 matchup and the overall sizes and weights are slightly different. However, these differences do not raise any new questions of safety or effectiveness.

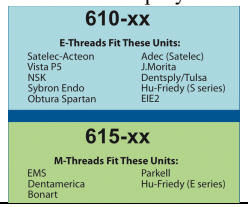
    The minor differences between the tün® ultrasonic tips under review and the predicate device cleared under K132609 are as follows:
    - The proposed device consistently references the ISO standard for thread sizes to interface with the ultrasonic generators (M3x0.5 or M3x0.6 thread), while the predicate device references one ISO and one American standard (M3x0.5 and #5-40 thread).
    - The proposed device explicitly states the intended users, the intended use environment, the targeted patient population, the operating & storage temperatures, compliance to specific standards, etc. while the predicate device does not.
      The proposed device states that they are to be "used on piezo ultrasonic endodontic and scaler units which operate in the range of 20,000hz – 35,000hz," while the predicate device states that they vibrate "at high frequencies (up to 40,000 Hz)."

    A table showing substantial equivalence to the predicate device follows:

| Item | Proposed Device: tün® ultrasonic tips Product Family | Predicate Device: EDS Ultrasonic Tips K132609 | Comments |
|---|---|---|---|
| **COMPARISON OF GENERAL INFORMATION / USES & INDICATIONS** | | | |
| Photograph |  |  | For Information Purposes only, but the images show that the Proposed Device is Substantially Equivalent in its overall shape/configurations to the predicate device. |
| FDA Product Code | ELC | ELC | Identical to the predicate.<br>Therefore, Substantially Equivalent |
| FDA Regulation Number | 872.4950 | 872.4950 | Identical to the predicate.<br>Therefore, Substantially Equivalent |
| FDA Regulation Class | Class II | Class II | Identical to the predicate.<br>Therefore, Substantially Equivalent |
| FDA Regulation Description | Scaler, Ultrasonic | Scaler, Ultrasonic | Identical to the predicate.<br>Therefore, Substantially Equivalent |
| Intended Use / Indication for Use (As statement appears in the 510(k) indications for use form) | tün® ultrasonic tips are intended for use by dental professionals for the removal of soft and hard tissue during endodontic root canal preparation procedures. They can also aid in the removal of endodontic posts and other intra-canal blockages. | EDS Ultrasonic Tips are intended for use by dental professionals for the removal of soft and hard tissue during endodontic root canal preparation procedures. They can also aid in the removal of endodontic posts and other intra-canal blockages. | Except for branding issues (tün® versus EDS), the Indication for Use statements are identical. Branding does not raise any new questions of safety of effectiveness.<br>Therefore, Substantially Equivalent |
| FDA Device Description (As it appears in the applicable FDA Summary Statement) | tün® ultrasonic tips are an accessory to a piezoelectric ultrasonic handpiece and scaler unit. These powered components are not included as part of the device submitted for application with the 510(k) submission. tün® ultrasonic tips are stainless steel and will be available in M3x0.5 and M3x0.6 thread with 6 different tip designs. 1 tip design is devised for post removal; the remaining 5 tips are designed for negotiating the various angles and directions of root canals. | EDS Ultrasonic Tips are an accessory to a piezoelectric ultrasonic handpiece and scaler unit. These powered components are not included as part of the device submitted for application with the 510(k) submission. EDS Ultrasonic Tips are stainless steel and will be available in M3x0.5 and #5-40 thread with 6 different tip designs. 1 tip design is devised for post removal; the remaining 5 tips are designed for negotiating the various angles and directions of root canals. | Except for branding issues (tün® versus EDS), and the use of thread standards (M3x0.6 vs #5-40), the Device Descriptions are identical. The proposed device consistently references the ISO standard for thread sizes, while the predicate device references one ISO and one American standard). Branding issues and citing different but equivalent standards for thread sizes do not raise any new questions of safety of effectiveness.<br>Therefore, Substantially Equivalent |
| Intended User(s) | Dentists, Endodontists, Oral surgeons, and Dental hygienists | Although not formally stated, assumed to be Dentists, Endodontists, Oral surgeons, and Dental hygienists | Although not known to be formally stated in the predicate's submission, the intended users are assumed to be identical to the predicate. |

| Item | Proposed Device: tün® ultrasonic tips Product Family | Predicate Device: EDS Ultrasonic Tips K132609 | Comments |
|---|---|---|---|
| | | | Therefore, Substantially Equivalent |
| Intended Use Environment | In dental clinics | Although not formally stated, assumed to be dental clinics | Although not known to be formally stated in the predicate's submission, the Intended Use Environment is assumed to be identical to the predicate.<br>Therefore, Substantially Equivalent |
| Contra-Indication(s) | There are no known contra-indications when used as recommended. | There are no known contra-indications when used as recommended. | Identical to the predicate.<br>Therefore, Substantially Equivalent |
| Warnings | Please refer to the instructions for use of the manufacturer of the piezoelectric ultrasonic unit. It is important to note that the different | Please refer to the instructions for use of the manufacturer of the piezoelectric ultrasonic unit. It is important to note that the different | Identical to the predicate.<br>Therefore, Substantially Equivalent |
| Precautions | • Do not start the piezoelectric ultrasonic generator with damaged ultrasonic tips.<br>• For best results, and your safety, the use of a visual aid is recommended.<br>• Do not heat above 275ºF/135ºC.<br>• Tips that have been distorted in any fashion should be discarded.<br>• To avoid overheating the dentin structures, do not apply continuous contact for more than 30 seconds.<br>• The tip must be tightened onto the ultrasonic handpiece prior to use. Please pay attention not to over tighten nor under tighten. | • Do not start the piezoelectric ultrasonic generator with damaged ultrasonic tips.<br>• For best results, and your safety, the use of a visual aid is recommended.<br>• Do not heat above 275ºF/135ºC.<br>• Tips that have been distorted in any fashion should be discarded.<br>• To avoid overheating the dentin structures, do not apply continuous contact for more than 30 seconds.<br>• The tip must be tightened onto the ultrasonic handpiece prior to use. Please pay attention not to over tighten nor under tighten. | Identical to the predicate.<br>Therefore, Substantially Equivalent |
| **COMPARISON OF STERILIZATION ISSUES** | | | |
| Sterilization Status | Provided non-sterile. | Provided non-sterile. | Identical Sterilization Status.<br>Therefore, Substantially Equivalent |
| Sterilization Instructions | tün ultrasonic tips are not sold sterile and must be cleaned and sterilized prior to each use.<br>A. Wipe tips with a cleaning disinfectant.<br>B. Cleaning –<br>Pre-clean using a high-quality, pH neutral, ultrasonic cleaning solution. Follow solution manufacturer's instructions.<br>Dry thoroughly with a towel and compressed air.<br>C. Steam Sterilization –<br>Place the tips to be sterilized in an autoclave pouch prior to sterilization. | EDS Ultrasonic Tips are not sold sterile and must be cleaned and sterilized prior to each use.<br>A. Wipe tips with a cleaning disinfectant.<br>B. Cleaning –<br>Pre-clean using a high-quality, pH neutral, ultrasonic cleaning solution. Follow solution manufacturer's instructions.<br>Dry thoroughly with a towel and compressed air.<br>C. Steam Sterilization –<br>Place the tips to be sterilized in an autoclave pouch prior to sterilization. | Except for branding issues (tün® versus EDS), the Sterilization Instructions are identical. Branding does not raise any new questions of safety of effectiveness.<br>Therefore, Substantially Equivalent |
| Sterilization Parameters | Gravity Steam Sterilizer:<br>• Temperature: 250o F/121o C.<br>• Cycle Time: 30 minutes<br>• Maximum Dry Time: 30 minutes<br>Prevacuum Steam Sterilizer: | Gravity Steam Sterilizer:<br>• Temperature: 250o F/121o C.<br>• Cycle Time: 30 minutes<br>• Maximum Dry Time: 30 minutes<br>Prevacuum Steam Sterilizer: | Identical Sterilization Parameters.<br>Therefore, Substantially Equivalent |

| Item | Proposed Device: tün® ultrasonic tips Product Family | Predicate Device: EDS Ultrasonic Tips K132609 | Comments |
|---|---|---|---|
| | • Temperature: 270o F/132o C.<br>• Cycle Time: 4 minutes<br>• Maximum Dry Time: 30 minutes | • Temperature: 270o F/132o C.<br>• Cycle Time: 4 minutes<br>• Maximum Dry Time: 30 minutes | |
| **COMPARISON OF OPERATING PRINCIPLES & MATERIALS** | | | |
| Operating Principle | tün tips interact with piezo ultrasonic hand piece and unit. tün tips are an accessory to a piezo ultrasonic hand piece and unit.<br>tün tips are used on piezo ultrasonic endodontic and scaler units which operate in the range of 20,000hz – 35,000hz. | Used in conjunction with piezoelectric ultrasonic handpiece and scaler. Ultrasonic energy vibrates tip at high frequencies (up to 40,000 Hz) | Identical Operating Principles with similar operational ranges.<br>Therefore, Substantially Equivalent |
| Comparison of Tip Shapes | Tip Shape EDS Tip<br>E1 Radiused Tip with diamond EDS 2/3<br>E2 Radiused Tip without diamond EDS 2/3<br>E3 Ball Tip EDS 4<br>E4 Football Tip EDS 4<br>E5 Disc-Shaped Tip EDS 5<br>E6 Short, Robust Tip EDS 1 | Tip Shape tün Tip<br>EDS 1 Short, Robust Tip E6<br>EDS 2 Radiused Tip E1/2<br>EDS 3 Radiused Tip II E1/2<br>EDS 4 Large Point Tip E3/4/5<br>EDS 5 Small Pointed Tip E1/2<br>EDS 6 N/A – Irrigation Tip No Direct Equivalent | Both the predicate device and the proposed device offer the various tip shapes that are commonly used in the industry. The differences in tip shape do not introduce any new questions of safety or effectiveness.<br>Therefore, Substantially Equivalent |
| Construction Materials | 17-4ph Stainless Steel<br>Alloy 17-4PH (UNS S17400), Type 630, is a chromium-nickel-copper precipitation-hardening martensitic stainless steel with an addition of niobium. 17-4PH combines high strength and hardness with good corrosion resistance. | 316 Stainless Steel<br>Alloy 316/316L (UNS S31600/ S31603) is a chromium-nickel- molybdenum austenitic stainless steel developed to provide improved corrosion resistance to Alloy 304/304L in moderately corrosive environments. It is often utilized in process streams containing chlorides or halides. The addition of molybdenum improves general corrosion and chloride pitting resistance. It also provides higher creep, stress-to-rupture and tensile strength at elevated temperatures. | The proposed device uses a Chromium:Nickel: Copper stainless steel alloy, while the predicate device uses a Chromium:Nickel:Molybdenum stainless steel alloy. The difference in materials reflect different manufacturing methods (sintering versus machining) and does not affect the overall safety or performance of the finished device.<br>Therefore, Substantially Equivalent |
| Coatings | Nickel Plating or<br>Diamond Nickel Plating | None | The proposed device is plated while the predicate device is not. This difference is a function manufacturing method and does not affect the overall safety or performance of the device. Note: The predicate device chosen by K132609 used Titanium Nitride and Zirconium Nitride as plating materials – see K960889.<br>Therefore, Substantially Equivalent |
| **COMPARISON OF CLINICAL USE / INTERACTIONS WITH OTHER DEVICES** | | | |
| Interaction with other products and/or items used with the product | tün instruments have been designed to function on most brands of Piezo-Electric type dental ultrasonic Scalers that use an M3x0.5 or M3x0.6 thread. Refer to your | EDS Ultrasonic Tips are an accessory to a piezoelectric ultrasonic handpiece and scaler unit with M3xO.5 or #5-40 threads | Both devices require the use of third-party ultrasonic scalers. These devices use one of two thread types either M3x0.5 or M3x0.6/#5-40. Functionally, the |

| Item | Proposed Device: tün® ultrasonic tips Product Family | Predicate Device: EDS Ultrasonic Tips K132609 | Comments |
|---|---|---|---|
| | ultrasonic machine owner's manual for further details on the use of these types of devices. | | devices are same.<br>Therefore, Substantially Equivalent |
| **COMPARISON OF PACKAGING SPECIFICATIONS / CONFIGURATIONS** | | | |
| Catalog Numbering | The catalog number schema uniquely identifies each variant as tun-e-X or tun-e-Xe<br>Where e-X = Satelec type threads and X = the tip style from 1 to 6<br>And e-Xe = EMS type threads and X = the tip style from 1 to 6. | The catalog number schema uniquely identifies each variant as 610-XX or 615-XX<br>Where 610 = E type threads; 615 = M type threads<br>And XX = the tip style from 01 to 06.<br>  | Both the proposed and predicate devices offer a total series of 6 tips that use two different thread styles for a total of 12 different tips. The proposed devices call M3x0.6 threads "Satelec" style, while the predicate calls them "E" style and proposed devices calls M3x0.5 threads "E" style, while the predicate calls them "M" style. Both devices use a formulaic catalog numbering system to encode for the 12 variants. Although the systems are different, no new issues of safety or effectiveness are introduced.<br>Therefore, Substantially Equivalent |
| Packaging Configurations | Sold as individual tips | Sold as individual tips | Identical to the predicate.<br>Therefore, Substantially Equivalent |
| Packaging Materials | Plastic tray | Plastic pouch | Identical to the predicate.<br>Therefore, Substantially Equivalent |
| **COMPARISON OF DIMENSIONAL SPECIFICATIONS** | | | |
| Dimensions | Each tip is approximately 12 mm long by 14 mm wide | Each tip is approximately 15 mm long by 20 mm wide | Similar overall dimensions. The minor variations do not introduce any new questions of safety or effectiveness. Therefore, Substantially Equivalent |
| Weight | Each tip weighs approximately 0.75 grams. | Each tip weighs approximately 1.2 grams. | Similar weight. The minor variations do not introduce any new questions of safety or effectiveness.<br>Therefore, Substantially Equivalent |
| **COMPARISON OF ENVIRONMENT SPECIFICATIONS** | | | |
| Operating Environment | Room Temperature | Not Known | Although the predicate device did not state its operating environment, the proposed device's operating environment does not raise any new questions of safety or effectiveness.<br>Therefore, Substantially Equivalent |
| Storage Environment | Room Temperature | Not indicated | Although the predicate device did not state its storage environment, the proposed device's storage environment does not raise any new questions of safety or effectiveness.<br>Therefore, Substantially Equivalent |
| **COMPARISON OF APPLIED STANDARDS** | | | |

| Item | Proposed Device: tün® ultrasonic tips Product Family | Predicate Device: EDS Ultrasonic Tips K132609 | Comments |
|---|---|---|---|
| Applicable Standards | • ISO 7405 Second edition 2008-12-15 *Dentistry - Evaluation of biocompatibility of medical devices used in dentistry* [Including: Amendment 1 (2013)] resulting in testing to:<br>  • ISO 10993-5:2009 / (R) 2014 *Biological Evaluation of Medical Devices-Part 5: Tests for in vitro cytotoxicity*<br>  • ISO 10993-10:2009 / (R) 2014 *Biological Evaluation of Medical Devices-Part 10: Tests for irritation and skin sensitization*<br>• ISTA 3A *General Simulation Performance Test Procedure: Packaged - Products for Parcel Delivery System Shipment 150lbs or less* | Not indicated / not known/cited | ISO 7405 Second edition is a recognized consensus standard for product code ELC and ISTA 3A is a widely used standard for evaluating packaging/shipping performance. The Summary Statement of the predicate device did not cite the use of any external standards. However, the proposed device's compliance with the cited standards only bolsters the argument for safety and effectiveness. Therefore, Substantially Equivalent |

14. Comparison Summary / Conclusions

Engineered endodontics believes the proposed tün® ultrasonic tips and its predicate, the EDS ultrasonic tips, cleared under K132609, are substantially equivalent in their intended use, intended users, intended use environment and indications for use. Furthermore, both devices have the same/equivalent technological characteristics, physical characteristics and applicable safety standards. The differences that exist between the devices, relating to their manufacturing methods, coatings and materials and minor shape variations are not significant and are therefore substantially equivalent.