Ms. Loretta Mooney  
Compliance Engineer  
Collesa/Wahledent Incorporated  
235 Ascot Parkway  
Cuyahoga Falls, Ohio 44223-3701

Re: K051660  
Trade/Device Name: Dentronix “DDS 7000” Rapid Dry Heat Sterilizer Sterilization  
Regulation Number: 21 CFR 880.6870  
Regulation Name: Dry Heat Sterilizer  
Regulatory Class: II  
Product Code: KMH  
Dated: June 21, 2005  
Received: June 23, 2005

Dear Ms. Mooney:

This letter corrects our substantially equivalent letter of August 4, 2005.

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 (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1090-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801); please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding, by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/samz/sammain.html

Sincerely yours,

[Signature]

Gina Lin, Ph.D
Director
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
## Premarket Notification [510(k)] Summary

<table>
<thead>
<tr>
<th>Owner and Contact</th>
</tr>
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</table>
| **Device Sponsor and Manufacturer:** Coltene/Whaledent, Inc.  
235 Ascot Parkway  
Cuyahoga Falls, Ohio 44223-3701  
**Contact Person:** Loretta Mooney  
235 Ascot Parkway  
Cuyahoga Falls, Ohio 44223  
330-916-8800 |

Summary prepared on June 15, 2005

<table>
<thead>
<tr>
<th>Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trade name</strong> – Dentronix DDS 7000 Rapid Dry Heat Sterilizer Sterilization System referred to as the “DDS 7000” for the remainder of this document</td>
</tr>
<tr>
<td><strong>Common name</strong> – Dry Heat Table Top Sterilizer</td>
</tr>
<tr>
<td><strong>Classification name</strong> – Sterilizer, Dry Heat</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Dentronix DDS 7000 Rapid Dry Heat Sterilizer Sterilization System is substantially equivalent to the Dentronix DDS 5000 Dry Heat Sterilization System, referred to as the “DDS 5000” for the remainder of this document, legally marketed per 510(k) K880322. The DDS 7000 utilizes the same accessories used by the predicate device.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>General Description</th>
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</table>
| The DDS 7000, like the DDS 5000, is a convective dry heat batch sterilizer capable of sterilizing unbagged dental instruments and cooling them for immediate use. It is designed for use with a dedicated rack system that provides for uniform loading to achieve optimum load distribution.  
The DDS 7000 is equipped with a replaceable HEPA filter to comply with ANSI/AAMI ST50: 2004 cooling requirements. The HEPA filter has a filtration efficiency of 99.7% for 0.3-micron particles.  
The DDS 7000 is a software-controlled device that allows for the user to preprogram options such as display units (Celsius or Fahrenheit), audible alarm enabled/disabled and safety interlock enabled/disabled. The DDS 7000 monitors the entire cycle and will provide diagnostic error codes in the event of any failure or disruption to the sterilization cycle. A printable log is available for the most recently performed cycle that includes pass/fail notification and error codes if applicable |
Intended Use

The DDS 7000 is a countertop convective dry heat sterilizer designed for use in Healthcare facilities for the sterilization of un-bagged dental instruments that can withstand exposure temperatures up to 216°C (420°F). There is a single software-controlled cycle that includes a warm-up and cool down phase in addition to the 3-minute sterilization (exposure) phase. Sterilize (exposure) starts when the RTD/control temperature reaches the operating temperature set point of 190°C (374°F). Complete cycle times average 34-44 minutes and are load dependent. The DDS 7000 achieves optimum results by uniform load distribution utilizing a dedicated rack and tray system as detailed below.

1) Maximum recommended loads for the DDS 7000-115 sterilizer:

   a) Maximum load for a four (4)-rack configuration is four (4) plier racks each holding nine (9) orthodontic pliers each for a total of thirty-six (36) pliers. Other maximum load configuration options are: 32 pliers on eight mini vertical racks; or 20 pliers and hand instruments on four Combo Racks -(OR)-(b) Maximum load for a full tray configuration is one (1) Horizontal Tray each holding up to six (6) orthodontic pliers or up to (12) single-handle hand instruments. Other maximum load combinations include: (5) orthodontic pliers with up to (2) single-handle hand instruments; or (4) orthodontic pliers with up to (4) single-handle hand instruments; or (3) orthodontic pliers with up to (6) single-handle hand instruments; or (2) Orthodontic pliers with up to (8) single-handle hand instruments; or (1) Orthodontic pliers with up to (10) single-handle hand instruments. -(OR)-(c) Maximum load for the one (1) half tray and two (2) racks is one (1) Half Tray holding three (3) Orthodontic pliers or six (6) single-handle hand instruments in combination with two (2) plier racks capable of holding nine (9) pliers each for a total of eighteen (18) pliers on plier racks. Other maximum load combinations include: (2) orthodontic pliers with up to (2) single-handle hand instruments in combination with two (2) plier racks capable of holding nine (9) pliers each for a total of eighteen (18) pliers on plier racks, or (1) orthodontic pliers with up to (4) single-handle hand instruments in combination with two (2) plier racks capable of holding nine (9) pliers each for a total of eighteen (18) pliers on plier racks.

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<table>
<thead>
<tr>
<th>Technological Characteristics</th>
<th>DDS 5000 / K880322</th>
<th>DDS 7000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method of organism Destruction</td>
<td>Dry heat (Forced air)</td>
<td>Dry heat (Forced air)</td>
</tr>
<tr>
<td>Method of heating</td>
<td>Electric element, mechanical convection</td>
<td>Electric element, mechanical convection</td>
</tr>
<tr>
<td>Sterilizing Temperature</td>
<td>375°F</td>
<td>190°C (374°F)</td>
</tr>
<tr>
<td>Sterilizing cycle time</td>
<td>6 minute plus warm-up and cool down</td>
<td>3 minute plus warm-up and cool down</td>
</tr>
<tr>
<td>Forced Air Cool Down</td>
<td>Yes – time monitored</td>
<td>Yes – temperature monitored</td>
</tr>
<tr>
<td>Controlled instrument</td>
<td>Yes, dedicated rack and trays</td>
<td>Same</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Feature</th>
<th>DDS 7000</th>
<th>DDS 5000</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Door Interlock</td>
<td>On 230 V Unit only</td>
<td>Standard on 115 V and 230 V Unit</td>
<td></td>
</tr>
<tr>
<td>Printer/PC COM Port</td>
<td>No</td>
<td>Yes, Allows Cycle log print out of last cycle</td>
<td></td>
</tr>
<tr>
<td>HEPA FilterAir During Cool Down</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Temperature Monitoring</td>
<td>Yes, LCD display</td>
<td>Yes, LED Display</td>
<td></td>
</tr>
<tr>
<td>Process Error Detection</td>
<td>No</td>
<td>Yes, Software monitors all cycle parameters and provides diagnostic error codes and audible alarm</td>
<td></td>
</tr>
<tr>
<td>User Option(s) Interface</td>
<td>No</td>
<td>Yes, options such as units of measure, door lock and use of the audible alarm can be set by the user</td>
<td></td>
</tr>
</tbody>
</table>

The chamber sizes are similar in size. The DDS 7000 is slightly taller due to the added HEPA filtration system.

Performance Testing

Temperature studies were performed on full, partial and empty chambers. Performance testing of the DDS 7000 was performed using Bacillus atrophaeus spore strips and inoculated tools using the same organism. Half cycle kills resulted in an overall 12-log reduction of spores and thus produces a $10^6$ sterility assurance level (SAL). This testing showed that the DDS 7000 is as safe and effective and performs as well if not better than the predicate device (DDS 5000).

Software Validation

The software was designed and validated to assure that the device is as safe and effective or better than the predicate device (DDS 5000). “General Principles of Software Validation; Final Guidance for Industry” and “FDA Staff and Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Final” were used in the development and validation of the device software.
Indications for Use

510(k) Number (if known): Unknown
Device Name: Dentronix DDS 7000 Rapid Dry Heat Sterilizer Sterilization System

Indications for Use:
The DDS 7000 is a countertop convective dry heat sterilizer designed for use in Healthcare facilities for the sterilization of un-bagged dental instruments that can withstand exposure temperatures up to 216°C (420°F). There is a single software-controlled cycle that includes a warm-up and cool down phase in addition to the 3-minute sterilization (exposure) phase. Sterilize (exposure) starts when the RTD/control temperature reaches the operating temperature set point of 190°C (374°F). Complete cycle times average 34-44 minutes and are load dependent. The DDS 7000 achieves optimum results by uniform load distribution utilizing a dedicated rack and tray system as detailed below.

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Prescription Use AND/OR Over-The-Counter Use x
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(Please do not write below this line-continue on another page of needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K057660