Dear Ms. Hong:

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. 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); 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 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Device Name
Dental Unit

Indications for Use (Describe)
The Dental Unit is intended to supply power to and serve as a base for dental devices; and accessories. It is intended for use in the dental clinic/office environment and used by trained dentists and/or dental technicians and assistants. This product is attached with a dental chair.

Type of Use (Select one or both, as applicable)
- [x] 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.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASIAStaff@fda.hhs.gov

"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."
510(k) Summary

This 510(k) Summary of 510(k) information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K142206

1. Date of Submission: 01/20/2015

2. Sponsor Identification

Zhuhai Siger Medical Equipment Co., Ltd
Building 2, No. 1 Chuangxin Yi Road, Tangjiawan Town, Zhuhai City, Guangdong, China

Establishment Registration Number: Not yet registered

Contact Person: Huisheng Wang
Position: General Manager
Tel: 86 13802677946
Fax: 86 756 3881011
Email: wanghs@siger.cn

3. Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net
4. **Proposed Device Identification**

   Proposed Device Name: Dental Unit  
   Proposed Device Model: U300, U500  
   Proposed Device Common Name: operative dental unit

   Regulatory Information:  
   Classification Name: Unit, Operative Dental  
   Classification: I  
   Product Code: EIA  
   Regulation Number: 21 CFR 872.6640  
   Review Panel: Dental

   Intended Use Statement:  
   “The Dental Unit is intended to supply power to and serve as a base for dental devices; and accessories. It is intended for use in the dental clinic/office environment and used by trained dentists and/or dental technicians and assistants. This product is attached with a dental chair.”

5. **Predicate Device Identification**

   510(k) Number: K130410  
   Product Name: Dental Unit with Chair S2310  
   Manufacturer: Xianyang North West Medical Instrument (Group) Co., Ltd

6. **Device Description**

   The proposed devices Dental Unit are well equipped dental unit, which are intended to supply power to and serve as a base for dental devices and accessories. They are intended for use in the dental clinic/office environment and used by trained dentists and/or dental technicians and assistants. The products are attached with dental chair.

   The proposed devices include two models, U300 and U500. Both of the two models mainly consist of instruments, instrument arm tray, cabinet group, operation light, operation light arm, assistant position, pedal switch, and patient chair.

7. **Non-Clinical Test Conclusion**

   Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:
- ISO 6875: 2011, Dentistry -- Patient chair

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

<table>
<thead>
<tr>
<th>Item</th>
<th>Proposed Devices</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Code</td>
<td>EIA</td>
<td>EIA</td>
</tr>
<tr>
<td>Regulation No.</td>
<td>21 CFR 872.6640</td>
<td>21 CFR 872.6640</td>
</tr>
<tr>
<td>Class</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Intended Use</td>
<td>The Dental Unit is intended to supply power to and serve as a base for dental devices; and accessories. It is intended for use in the dental clinic /office environment and used by trained dentists and/or dental technicians and assistants. This product is attached with a dental chair.</td>
<td>The Dental Unit with Chair is intended to supply power to and serve as a base for dental devices and accessories. It is intended for use in the dental clinic /office environment and used by trained dentists and/or dental technicians and assistants. This product is attached with a dental chair.</td>
</tr>
<tr>
<td>Features</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating Light</td>
<td>Halogen</td>
<td>LED</td>
</tr>
<tr>
<td>Connection Joint</td>
<td>Comply with ISO9168</td>
<td>Comply with ISO9168</td>
</tr>
<tr>
<td>Water Heating</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Operation Method</td>
<td>Control Panel / Assistant Control Panel / Foot Controller</td>
<td>Control Panel / Assistant Control Panel / Foot Controller</td>
</tr>
<tr>
<td>Power Supply</td>
<td>110V</td>
<td>110V</td>
</tr>
<tr>
<td>Frequency</td>
<td>50/60Hz</td>
<td>50/60Hz</td>
</tr>
</tbody>
</table>
### Power (with dental chair)

<table>
<thead>
<tr>
<th>Power</th>
<th>900VA</th>
<th>400VA</th>
</tr>
</thead>
</table>

### Pressure of Water Supply

<table>
<thead>
<tr>
<th>Pressure of Water Supply</th>
<th>200 kPa ~ 400 kPa</th>
<th>0.2MPa-0.4MPa</th>
</tr>
</thead>
</table>

### Pressure of Air Supply

<table>
<thead>
<tr>
<th>Pressure of Air Supply</th>
<th>≥550 kPa</th>
<th>0.55MPa</th>
</tr>
</thead>
</table>

### Dental Chair

<table>
<thead>
<tr>
<th>Dental Chair</th>
<th>Loading Capacity</th>
<th>135Kg</th>
<th>200Kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Movement Range (Chair)</td>
<td>420-820 MM</td>
<td>390mm-740mm</td>
</tr>
<tr>
<td></td>
<td>Movement Range (Backrest)</td>
<td>0°~80°</td>
<td>1°~70°</td>
</tr>
<tr>
<td></td>
<td>Movement Range (Headrest)</td>
<td>200MM</td>
<td>150mm</td>
</tr>
</tbody>
</table>

### Accessories can be attached to the device

<table>
<thead>
<tr>
<th>Accessories can be attached to the device</th>
<th>Handpiece / Scaler / Curing Light / Syringe</th>
<th>Handpiece / Scaler / Curing Light / Three-way-Syringe</th>
</tr>
</thead>
</table>

### Performance Standards

<table>
<thead>
<tr>
<th>Performance Standards</th>
<th>Comply with ISO7494-1, ISO7494-2 and ISO6875</th>
<th>Comply with ISO7494-1, ISO7494-2 and ISO6875</th>
</tr>
</thead>
</table>

### Rate of Water Suction

<table>
<thead>
<tr>
<th>Rate of Water Suction</th>
<th>Suction</th>
<th>≥ 1L/min</th>
<th>1 L/min</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Silva Ejector</td>
<td>&gt; 750mL/min</td>
<td>750ml /min</td>
</tr>
</tbody>
</table>

### Electrical Safety

<table>
<thead>
<tr>
<th>Electrical Safety</th>
<th>Comply with IEC 60601-1</th>
<th>Comply with IEC 60601-1</th>
</tr>
</thead>
</table>

### EMC

<table>
<thead>
<tr>
<th>EMC</th>
<th>Comply with IEC 60601-1-2</th>
<th>Comply with IEC 60601-1-2</th>
</tr>
</thead>
</table>

### Patient Contact Material

<table>
<thead>
<tr>
<th>Patient Contact Material</th>
<th>Armrest: PU Leather for patient chair: PVC Syringe: Stainless steel Tubes: TPU</th>
<th>PU, PVC, Polyamide, ABS, Stainless steel</th>
</tr>
</thead>
</table>

The proposed devices, Dental Unit U300 and U500, are determined to be Substantially Equivalent (SE) to the predicate device, Dental Unit with Chair S2310 (K130410), with respect to intended use, technological characteristics and principles of operation.