Applicant: KaVo Dental Corporation
Address: 340 East Main Street
          Lake Zurich, IL 60047
          USA
Phone Number: 847-550-6800
Fax Number: 847-550-6825
Contact Person: Marl Lambert
Summary Prepared: October 4, 2007
Name of Device: KaVO GENTLEray 980
Trade Name: GENTLEray 980
Common Name: GENTLEray
Classification Name: Laser surgical instrument for use in general and plastic surgery
                  and in dermatology
CFR Number: 21 CFR §878.4810
Product Code: GEX
Product Description: The GENTLEray 980 Diode Dental Laser System is a portable
                   instrument intended for ablating, incising, excising, and
                   coagulating intraoral soft tissue (including the marginal and
                   interdental gingiva) using a contact fiber optic delivery system.
Intended Use: Intra- and extra-oral surgery including incision, excision,
              hemostasis, coagulation and vaporization of soft tissue.
              The GENTLEray 980 Diode Dental Laser System is intended for
              use in the following procedures: Frenectomy, Frenotomy,
              Biopsy, Operculectomy, Implant Recovery, Gingivectomy,
              Gingivoplasty, Gingival Troughing, Crown Lengthening,
              Hemostasis of Donor Site, Removal of Granulation Tissue,
              Laser-assisted Flap Surgery, Debridement of Diseased Epithelial
              Lining, Incisions and Draining of Abscesses, Tissue Retraction
              for Impressions, Papillectomy, Vestibuloplasty, Excision of
              Lesions, Leukoplakia, Exposure of Unerupted/Partially Erupted
              Teeth, Removal of Hyperplastic Tissues, Treatment of Aphthous
              Ulcers, Sulcular Debridement, Pulpotomy, Pulpotomy as an
              Adjunct to Root Canal Therapy, and Light Activation of
              Bleaching Materials.
Performance Standards:

The GENTLEray 980 Diode Dental Laser System complies with the appropriate sections of 21 CFR §1010 and 21 CFR §1040.

Substantial Equivalence:

The GENTLEray 980 Diode Dental Laser System has the same intended use and the same or substantially equivalent technical specifications and mechanism of action as compared with the named predicated devices. The KaVo GENTLEray 980 Diode Laser is substantially equivalent to the Ceramoptec Ceralas D15 (K983058, K991891) sold latterly under the BioLitec brand name SmilePro™ 980, the ADT Diolase 980 D Laser System (K023547) and the Elexxion Claros (K063152). Performance testing to validate the safety and effectiveness of the GENTLEray 980 Diode Dental Laser System includes electrical safety, electromagnetic compatibility, and validation testing of both hardware and software functions. The comparison of specifications are as follows:

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Proposed Device</th>
<th>Predicate Device</th>
<th>Predicate Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wavelength</td>
<td>980 nm</td>
<td>980 nm</td>
<td>980 nm</td>
<td>810 nm</td>
</tr>
<tr>
<td>Output Power</td>
<td>12W</td>
<td>15W</td>
<td>15 W</td>
<td>30 W</td>
</tr>
<tr>
<td>Power Range</td>
<td>0.4 - 12W</td>
<td>1-15W</td>
<td>2 - 15W</td>
<td>0.01W - 30 W</td>
</tr>
<tr>
<td>Increments</td>
<td>2 - 1W</td>
<td>1W</td>
<td>2 - 1W</td>
<td>0.01W - 1 W</td>
</tr>
<tr>
<td>Operating Modes</td>
<td>Pulsed or Continuous</td>
<td>Pulsed or Continuous</td>
<td>Pulsed or Continuous</td>
<td>Pulsed or Continuous</td>
</tr>
<tr>
<td>Pulse Duration ON</td>
<td>25μs to 99.9 Sec.</td>
<td>0.01 to 99.9 Sec.</td>
<td>0.01 to 99.9 Sec.</td>
<td>25μs to 99.9 Sec.</td>
</tr>
<tr>
<td>Pulse Duration OFF</td>
<td>25μs to 99.9 Sec.</td>
<td>0.01 to 99.9 Sec.</td>
<td>0.01 to 99.9 Sec.</td>
<td>25μs to 99.9 Sec.</td>
</tr>
<tr>
<td>Frequency</td>
<td>20,000 Hz</td>
<td>100 Hz</td>
<td>100 Hz</td>
<td>20,000 Hz</td>
</tr>
<tr>
<td>Aiming beam</td>
<td>635 nm, &lt;1mW, Red</td>
<td>635 nm, 4mW, Red</td>
<td>635 nm, 4mW, Red</td>
<td>635 nm, 4mW, Red</td>
</tr>
<tr>
<td>Cooling</td>
<td>Air Cooled</td>
<td>Air Cooled</td>
<td>Air Cooled</td>
<td>Air Cooled</td>
</tr>
<tr>
<td>Weight</td>
<td>9 lbs. (4.5kg)</td>
<td>15 lbs. (9kg)</td>
<td>11 lbs. (5kg)</td>
<td>48 lbs. (22kg)</td>
</tr>
<tr>
<td>Dimensions</td>
<td>10.5&quot; x 7&quot; x 6&quot;</td>
<td>14&quot; x 9&quot; x 7&quot;</td>
<td>14&quot; x 9&quot; x 3&quot;</td>
<td>33&quot; x 18&quot; x 20&quot;</td>
</tr>
<tr>
<td>Power Requirements</td>
<td>100 - 240 V</td>
<td>110/220 V</td>
<td>110/220 V</td>
<td>110/220 V</td>
</tr>
<tr>
<td>Sterilization Methods</td>
<td>Steam Autoclave</td>
<td>Steam Autoclave</td>
<td>Steam Autoclave</td>
<td>Steam Autoclave</td>
</tr>
<tr>
<td>Irrigant Supply</td>
<td>Peristaltic Pump</td>
<td>Peristaltic Pump</td>
<td>Peristaltic Pump</td>
<td>None</td>
</tr>
<tr>
<td>incision and excision, Hemostasis and coagulation, Implant recovery, Incision and drainage of abscesses, Leukoplakia, Opaculcetomy, Oral papillectomies, Pulpotomy, Pulpotomy as an Adjunct to root canal therapy, Reduction of gingival hypertrophy, Soft tissue crown lengthening, Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa, and Vestibuloplasty. *For use on adult and pediatric patients Laser Periodontal Procedures Laser soft tissue curettage, Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket, Removal of highly inflamed edematous tissue affected by bacterial penetration of the pocket lining and junctional epithelium, Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility) Tooth Whitening Laser assisted whitening/bleaching of teeth, Light activation for bleaching materials for teeth whitening.</td>
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</tr>
</tbody>
</table>

**Conclusion:** After analyzing both bench and user testing data, it is the conclusion of Kavo that the GENTLEray 980 Diode Laser System is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.
Kavo America
% Intertek Testing Services
Mr. Daniel W. Lehtonen
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K072262
   Trade/Device Name: GENTLEray 980 Diode Laser System
   Regulation Number: 21 CFR 878.4810
   Regulation Name: Laser surgical instrument for use in general and plastic surgery and
                    and in dermatology
   Regulatory Class: II
   Product Code: GEX
   Dated: October 10, 2007
   Received: October 11, 2007

Dear Mr. Lehtonen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it
may be subject to such 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 1000-1050.
This letter will allow you to begin 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" (21CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): KO 72262

Device Name: GENTLEray 980 Diode Laser System

Indications for Use:

Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D)
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number KO 72262