Subject Device Description

The new Diego RF Powered Dissector and Drill System Console is identical to the console cleared in 510(k) # 020594 (3.08.02). However an additional panel was added to operate the current handpieces with new RF blades that can provide coagulation in addition to powered dissection. Other than coagulation during procedures, there are no new indications for use.

Applicable 510(k)s – Predicate Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>FDA Clearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diego Powered Dissector and Drill</td>
<td>Gyrus ENT LLC</td>
<td>K020594</td>
</tr>
<tr>
<td>System</td>
<td>Bartlett, TN 38133</td>
<td></td>
</tr>
<tr>
<td>Smith &amp; Nephew Dyonics® ElectroBlade™</td>
<td>Smith &amp; Nephew, Inc.</td>
<td>K994385</td>
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<tr>
<td>Arthroscopy System</td>
<td>Endoscopy Division</td>
<td>K012314</td>
</tr>
<tr>
<td>Gyrus ENT Plasmacision</td>
<td>Andover, MD 001810</td>
<td>K031675</td>
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<tr>
<td>Arthrocare ENTEC Coblator Surgery</td>
<td>Arthocare Corporation</td>
<td>K030108</td>
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<tr>
<td>System</td>
<td>Sunnyvale, CA 94085</td>
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<tr>
<td>Surgitron IEC II</td>
<td>Elliman International</td>
<td>K001986</td>
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<td></td>
<td>Hewlett, NY 11557</td>
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</table>
**Subject Device Intended Use**

The Diego™ RF Powered Dissector and Drill System's intended use is the cutting and removal of bone and tissue in general ENT, Head & Neck, and otoneurologic procedures.

Sinus applications include:
- ethmoidectomy/sphenoethmoidectomy
- polypectomy
- septoplasty and
- procedures such as
  - the removal of septal spurs
  - antrostomy,
  - frontal sinus trephination and irrigation
  - frontal sinus drill-out
  - endoscopic DCR
  - trans-sphenoidal procedures

Nasopharyngeal/laryngeal procedures would comprise
- adenoidectomy:
- laryngeal lesion de-bulking
- laryngeal polypectomy
- tracheal procedures
- tonsillectomy

Head & neck procedures would encompass:
- soft tissue shaving
- rhinoplasty (narrowing of the bony vault and revision of the bony pyramid)
- removal of fatty (adipose) tissue (lipodebridement) in the maxillary and mandibular regions of the face
- acoustic neuroma removal

Otology procedures would include
- mastoidectomy
- mastoidotomy
Comparison Chart of Power Ratings

Diego RF Powered Dissector and Drill System
Vs.
Gyrus ENT Plasmacision vs. Arthrocare ENTeC Coblation Plastma Surgery vs. Ellman Surgitron IEC

<table>
<thead>
<tr>
<th></th>
<th>Diego RF Gyus ENT (K034004)</th>
<th>Gyrus ENT Plasmacision (K021777)</th>
<th>Arthrocare ENTeC Coblation Plastma Surgery (K030108)</th>
<th>Ellman Surgitron IEC (K001986)</th>
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</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>General ENT, Head &amp; Neck, and Otoneurologic Procedures</td>
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<td>General ENT Procedures</td>
<td>General ENT Procedures</td>
</tr>
<tr>
<td>Functions</td>
<td>Tissue Removal and RF Coagulation</td>
<td>Tissue Removal and RF Coagulation</td>
<td>Ablation, Resection and Coagulation of Soft Tissue and Hemostasis of Blood Vessels</td>
<td>Resection, Ablation, and Coagulation of Soft Tissues and Hemostasis of Blood Vessels</td>
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<tr>
<td>Default Power Rating</td>
<td>10 Watts</td>
<td>30 Watts</td>
<td>284 Watts</td>
<td>Cut 100 Watts</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cut/Coag 75 Watts</td>
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<td>Hemo 35 Watts</td>
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<td>Fulgurate 35 Watts</td>
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<td>Bipolar 40 Watts</td>
</tr>
<tr>
<td>Maximun Power Rating</td>
<td>40 Watts</td>
<td>40 Watts</td>
<td>284 Watts</td>
<td>100 Watts</td>
</tr>
</tbody>
</table>
Dear Ms. Farage:

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 (301) 594-4613. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use:

510(k) Number:

Device Name: Diego™ RF Powered Dissector and Drill System

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Prescription Use AND/OR Over-The-Counter Use
(21 CFR 801 Subpart D) (21 CFR 807 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 Ophthalmic Ear, Nose and Throat Devices

510(k) Number K034004