



Food and Drug Administration  
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March 24, 2016

Carevature Medical, Ltd.  
Ms. Orly Maor  
Company Consultant  
42<sup>nd</sup> Tvuot Haarets Street  
Tel Aviv, Israel 6954648

Re: K153519

Trade/Device Name: DReal™  
Regulation Number: 21 CFR 882.4310  
Regulation Name: Powered Simple Cranial Drills, Burrs, Trephines, and Their Accessories  
Regulatory Class: Class II  
Product Code: HBE  
Dated: February 9, 2016  
Received: February 11, 2016

Dear Ms. Orly Maor:

This letter corrects our substantially equivalent letter of March 16, 2016.

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Carlos L. Peña 

Carlos L. Peña, PhD, MS  
Director  
Division of Neurological  
and Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K153519

Device Name

DReal™

Indications for Use (Describe)

The Carevature DReal™ is intended to be used with high-speed compatible electric and pneumatic motors. When used with these motors, it is intended to cut bone by drilling, reaming, decorticating, shaping, dissecting, shaving and smoothing for neurosurgical and spinal applications. Specific applications include laminectomy/laminotomy and craniotomy/craniectomy/ skull base cuts < 1cm3.

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.

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## **Traditional Premarket Notification Submission – 510(k) Summary**

**DReal™**

**510(k) Number K153519**

### **I. SUBMITTER**

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Date Prepared: February 26, 2016

### **II. DEVICE**

Name of Device: DReal™  
Common or Usual Name: DReal™  
Classification Name: drills, burrs, trephines & accessories (simple, powered)  
CFR: 21 CFR §882.4310  
Regulatory Class: II  
Product Code: HBE

### **III. PREDICATE DEVICE**

The predicate device is the Stryker Corporation Stryker MIS Attachments and Cutting Accessories cleared under K143540 (product code HBE, Regulation No. 21 CFR §882.4310).

### **IV. DEVICE DESCRIPTION**

The DReal™ is a handheld bone-removal device based on a rotating cutter, with a protective shield (hood) partially covering the cutter; following its indications for use, it is designed to cut bone < 1 cm<sup>3</sup>.

The DReal™ comprises a handpiece with a plastic grip (“handle”) and a central shaft that curves at its distal end (“tip”). The curved tip is equipped with an active, drill-like



cutter that is protected by an extension of the central shaft as a protective shield. The DReal™ has two models, with different angles of curvature at the distal end: Short 45° and Long 75°.

Located in the proximal end of the handle, is the motor adaptor (the motor is not part of the supplied product).

The DReal™ principles of operation are the same as any other bone cutting tool, as well as the predicate device; it uses electrical or pneumatic power to rotate a cutting element that is approximated to the bone requiring cutting.

The DReal™ has an irrigation port on its handle that connects to irrigation source. Irrigation should be running at all times while the DReal™ is active. In case of irrigation malfunction, irrigation can be added externally as with any high-speed, rotating power device, including the predicate.

The DReal™ can be powered by an electric or pneumatic motors using a ‘micro’ adaptor as per ISO 3964; however, it can rotate only clockwise (right-hand, or Forward).

The following motor system (Class II, Product Code HBE) was validated for use with the DReal™:

- Stryker Consolidated Operating Room Equipment (CORE) -K112593

## **V. INDICATIONS FOR USE**

The Carevatura DReal™ is intended to be used with high-speed compatible electric and pneumatic motors. When used with these motors, it is intended to cut bone by drilling, reaming, decorticating, shaping, dissecting, shaving and smoothing for neurosurgical and spinal applications. Specific applications include laminectomy/laminotomy and craniotomy/craniectomy/ skull base cuts < 1cm<sup>3</sup>.

## **VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

A substantial equivalence table, which summarizes the similarities and differences between the DReal™ and the predicate device, is provided below.



	Carevatura Medical DReal™	Stryker MIS Attachments and Cutting Accessories	SE JUSTIFICATION
<b>510(k) Number</b>	K153519	K143540	—
<b>Manufacturer</b>	Carevatura Medical Ltd.	Stryker Corporation	—
<b>Product Code</b>	HBE	HBE, ERL	<b>Same</b>
<b>CFR</b>	§882.4310	§882.4310, §874.4240	<b>Same</b>
<b>Intended Use</b>	<p>The Carevatura DReal™ is intended to be used with high-speed compatible electric and pneumatic motors</p> <p>When used with these motors, it is intended to cut bone by drilling, reaming, decorticating, shaping, dissecting, shaving and smoothing for neurosurgical and spinal applications.</p> <p>Specific applications include laminectomy/laminotomy and craniotomy/craniectomy/ skull base cuts &lt; 1cm<sup>3</sup>.</p>	<p>The MIS Attachments and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE Console and electric and pneumatic motors</p> <p>When used with these motors, the MIS Attachments and Cutting Accessories are intended to cut bone in the following manner: drilling, reaming, decorticating, shaping, dissecting, shaving, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT)/Otorhinolaryngology; and Endoscopic applications.</p> <p>Specific applications include Craniotomy/Craniectomy, Laminotomy/Laminectomy, Minimally Invasive Surgery (MIS) Spine, Expanded Endonasal Approach (EEA)/Anterior Skull Base/ Endoscopic/Transnasal/Transphenoidal, and Orthopedic Spine. These devices are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.</p>	<p><b>Same-Substantially equivalent</b></p> <p><b>Different</b> The DReal™ has limited indications than the Stryker MIS attachments. The specific indications are a subset of already cleared indications for the predicate device.</p>

	Carevatura Medical DReal™	Stryker MIS Attachments and Cutting Accessories	SE JUSTIFICATION
<b>Patient Population</b>	General Prescription medical device	General Prescription medical device	<b>Same</b>
<b>Function</b>	<ul style="list-style-type: none"> <li>The subject Carevatura DReal™ models act as an interface between the high speed motors and the cutting accessories</li> <li>Carevatura DReal™ models are intended as a location for the user to hold and grip the device system</li> </ul>	<ul style="list-style-type: none"> <li>The predicate Stryker MIS Attachments act as an interface between the high speed motors and the cutting accessories</li> <li>The predicate MIS attachments are intended as a location for the user to hold and grip the device system. MIS Attachments and Cutting Accessories are intended to cut bone and used in the preparation for the placement of screws, metal, wires, pins, and other fixation devices</li> </ul>	<b>Same</b>
<b>Contraindications</b>	None known	None known	<b>Same</b>
<b>Type of operation</b>	Open surgical procedures	Open surgical procedures	<b>Same</b>
<b>Conditions for Use</b>	DReal™- Single Use	Attachments -Reusable Cutting accessories - Single use	<b>Same</b> Carevatura DReal™ devices are unified attachments and cutting accessories therefore, a single use
<b>Sterilization</b>	DReal™- supplied sterile, gamma irradiated	Attachments- sterilized by the user Cutting accessories — supplied sterile, gamma irradiated	<b>Similar</b> Carevatura DReal™ devices are unified attachments and cutting accessories therefore, sterilized by the manufacturer

	Carevature Medical DReal™	Stryker MIS Attachments and Cutting Accessories	SE JUSTIFICATION
<b>Main Materials</b>	<p>Commonly used medical grade metals and plastics:</p> <ul style="list-style-type: none"> <li>• The handle is made of Steralloy, a USP-6 plastic material</li> <li>• The central shaft is made of medical grade stainless steel</li> <li>• The cutter is made of medical grade stainless steel</li> </ul>	Commonly used medical grade metals and plastics	<p><b>Same</b></p> <p>Both the subject and the predicate are comprised of similar materials.</p> <p><b>Different</b></p> <p>The DReal™ has no color strip; instead, the various models are designated on the single-use outer and inner-packaging.</p>
<b>Packaging Configuration</b>	Carevature DReal™ products - double sterile sealed pouches and corresponding cardboard box.	<p>Attachments - Retention insert in a rigid carton</p> <p>MIS Cutting Accessories – sealed chevron style pouch sterile barrier system</p>	<p><b>Similar</b></p> <p>Carevature DReal™ models are unified attachments and cutting accessories therefore, packed in sterile sealed way</p>
<b>Available Style</b>	Curved, Angled (45° and 75°), partially-hooded burr	Straight, Curved, Angled	<p><b>Similar</b></p> <p>The curve and angle of the tip are intended to improve its access and visibility</p> <p><b>Different</b></p> <ul style="list-style-type: none"> <li>• The DReal™ possesses a sharper angulation near the distal end</li> <li>• The DReal™ possesses a partially-hooded burr to provide protection for surrounding tissue</li> </ul>

	Carevature Medical DReal™	Stryker MIS Attachments and Cutting Accessories	SE JUSTIFICATION
<b>Driving motor</b>	The Carevature DReal™ models were validated to be used with the Stryker Consolidated Operating Room Equipment (CORE Console and electric motors)	The MIS Attachments and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE Console and electric or pneumatic motors)	<b>Same</b>
<b>Head Style Offering</b>	Match Head	Round, Diamond, Match Head	<b>Similar</b>
<b>Diameter/Head Size</b>	2.5 mm	1.5 mm - 5.0 mm	<b>Similar</b>
<b>Length</b>	Shaft length 11cm	Two lengths 13 and 16 cm	<b>Similar</b>
<b>Motor power supply</b>	Electric and Pneumatic	Electric and Pneumatic	<b>Same</b>
<b>Speed</b>	10,000-40,000 rpm	5,000-75,000 rpm	<b>Similar</b>
<b>Pneumatic Pressure Recommendation</b>	120 psi (pounds per square inch)	120 psi (pounds per square inch)	<b>Same</b>
<b>Source of Activation</b>	Footswitch	Handswitch and Footswitch	<b>Similar</b>
<b>Performance</b>	<ol style="list-style-type: none"> <li>1. Shelf life testing</li> <li>2. Temperature Testing</li> <li>3. Slippage testing</li> <li>4. Simulated distribution testing transportation validation (Chatter testing)</li> <li>5. Simulated use testing</li> <li>6. Fatigue test</li> <li>7. Motor compatibility</li> <li>8. Excessive vibrations</li> </ol>	<ol style="list-style-type: none"> <li>1. Shelf life testing</li> <li>2. Temperature Testing</li> <li>3. Slippage testing</li> <li>4. Chatter testing</li> <li>5. Whip testing</li> </ol>	<b>Same</b> Whip test was deemed unnecessary due to the product design. Whipping effect is inherently limited to an acceptable value.



## VII. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination:

### **Biocompatibility testing**

An evaluation of biocompatibility was performed in compliance with ISO 10993-1.

The biocompatibility tests are listed in the table below:

<b>Test</b>	<b>Results</b>	<b>Conclusions</b>
GLP Cytotoxicity per ISO 10993-5	Less than grade 2 (mild reactivity)	Non-cytotoxic
ISO- intracutaneous in Rabbits (irritation) per ISO 10993-10	The difference between each test article extract overall mean score and corresponding control was 0.0 and 0.1 for test articles extract	Not irritant
Sensitization per ISO 10993-10	The test article showed no evidence of causing delayed dermal contact in the guinea pig	Not considered a sensitizer
Systemic toxicity per ISO 10993-11	No mortality or evidence of systemic toxicity from the extracts injected into mice	Nontoxic
Systemic toxicity USP pyrogen Study per ISO 10993-11	The total rise of rabbit temperatures was within acceptable USP limits	Nonpyrogenic
LAL test per NAMSA LAL SOP	Less than 0.06 EU/ml	Acceptable

All tests were successfully completed.

### **Sterilization, Packaging and Shelf Life Testing**

Sterilization validation testing was performed to demonstrate compliance with ISO 11137-1. In addition, shelf life and packaging testing were performed to support the labeled shelf life. All tests, including packaging integrity and simulated use (performance), were performed after simulated distribution testing (transportation validation) and successfully completed.



## Performance Testing

Performance testing included the following:

Test	Test Method Summary	Results
Simulated use testing	To demonstrate the performance of the DReal™ for its intended use: activation of the DReal™ on a hard-tissue model to show efficacy (material removal), durability and integrity for the removal of material needed with the device' indications in clinical settings.	The device passed the test. The acceptance criteria were met.
Temperature Testing	To demonstrate the compliance of the DReal™ to safety requirements derived from tissue necrosis	The device passed the test. The acceptance criteria were met.
Slippage testing	To demonstrate the compatibility of the DReal™ to the specified motors	The device passed the test. The acceptance criteria were met.
Simulated distribution testing transportation validation (Chatter testing)	To demonstrate the compatibility of the DReal™ to ASTM D4169-09 and ASTM D4332-13	The device passed the test. The acceptance criteria were met.
Fatigue test	To demonstrate the durability of the DReal™ for its intended use. Method: Activation of the DReal™ on a hard-tissue (bone) to show durability and integrity needed with the device' indications in clinical settings.	The device passed the test. The acceptance criteria were met.
Motor compatibility	To demonstrate the compatibility of the DReal™ to the specified motors	The device passed the test. The acceptance criteria were met. The motors that are approved appears on the device IFU
Excessive Vibration	To demonstrate the compatibility of the DReal™ to the specified motor without malfunction	The device passed the test. The acceptance criteria were met.
Animal Feasibility Test	To investigate the safety and performance of the DReal™ for its intended use in the spine. One live adult (7 months) pig was used. Intra-operative performance, gross bone volume reduction, and histopathological sections were observed.	The device passed the test. The acceptance criteria were met.



<b>Test</b>	<b>Test Method Summary</b>	<b>Results</b>
Cadaver Feasibility Test	To investigate the performance of the DReal™ for its intended use in the spine. One skeletally mature human cadaver was used. Gross bone volume reduction was observed.	The device passed the test. The acceptance criteria were met.

**Conclusions:**

The tests met the predefined acceptance criteria and passed.

**VIII. CONCLUSIONS**

The DReal™ was determined to be substantially equivalent to the predicate device.