



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 25, 2016

Grace Medical, Inc.
c/o Mr. Dave Yungvirt, CEO
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, NJ 07041

Re: K161376

Trade/Device Name: DragonFly Surgical Drill System
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, Nose, and Throat Electric or Pneumatic Surgical Drill
Regulatory Class: Class II
Product Code: ERL
Dated: August 8, 2016
Received: August 10, 2016

Dear Mr. Yungvirt:

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,

Eric A. Mann -S

for Malvina B. Eydelman, 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 (if known)

K161376

Device Name

DragonFly™ Surgical Drill System

Indications for Use (Describe)

The DragonFly™ Surgical Drill System has been designed for the light drilling of bones as part of surgical operations such as stapedotomy or ossiculoplasty.

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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510(k) Summary

Date Prepared: Aug 25th , 2016

Submitter: Grace Medical, Inc.
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Contact Person: William Graham
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Device Name:
Proprietary Name: DragonFly™ Surgical Drill System
Common Name(s): Electrical surgical drill, ENT drill burs

Classification Name: Drill, Surgical, ENT (electric or pneumatic) including handpiece
(21 CFR 874.4250, Product Code ERL) Class II

Bur, Ear, Nose and Throat
(21 CFR 874.4140, Product Code EQJ), Class I

Primary Predicate Device: OSSEOSTAP Microdrill, FDA Clearance K143492

Predicate Device(s):

Device	Classification	Manufacturer
Skeeter Ultra-Lite Oto-Tool Drill (Accessory of K041523)	874.4250, ERL, Class II Drill, Surgical, ENT (electric or pneumatic) including handpiece (21 CFR 874.4250, Product Code ERL)	Medtronic Xomed, Inc.
OSSEOSTAP Microdrill	874.4250, ERL Class II Drill, Surgical, ENT (electric or pneumatic) including handpiece (21 CFR 874.4250, Product Code ERL)	Shenzhen Medical

Device Description

The DragonFly™ Surgical Drill System consists of a small surgical power tool (handpiece); a battery powered footswitch for control of speed and direction; various cutting instruments (burs); angled adaptors to adjust the angle between the handpiece and the bur; and a sterilization tray. Accessories include a battery charger and a battery replacement kit.

Principles of Operation

The **footswitch** serves as the power control system and is used to control direction (Forward and Reverse) and handpiece speed (proportional to pedal position). Energy is supplied by rechargeable batteries contained within the footswitch. The **handpiece** contains a dc motor with a cylindrical magnet mounted to the drive shaft. It has an integrated handpiece power cable that connects to the footswitch cable via a push/pull Lemo connector. Interchangeable **angled adaptors** (15, 25, or 35 degrees) hold the cutting tool or bur in proper relation to the handpiece. A combination of friction and magnetic attraction keep the bur in place.

Unique Features

InvisiDrive™ - Transfer of power from the handpiece to the cutting tool is achieved via a magnetic drive system termed InvisiDrive™. More specifically, a transversely magnetized magnet mounted to the motor shaft magnetically links to a similar magnet mounted to the drive shaft of the bur. This creates a magnetic gear that requires no physical contact between motor and cutting tool.

BurShield™ - Some cutting tools have a sliding external guard termed BurShield™ which can be positioned to partially or completely shield the bur in order to protect tissue or packing material from coming into contact with the bur.

Sterilization Overview

The handpiece with cable, angled adaptors, and sterilization tray are autoclavable and intended for use in the sterile field. They should be thoroughly cleaned and sterilized before use. The sterilization tray is designed to hold (3) angled adaptors and the handpiece with cable. Burs are provided sterile and labeled for single use only. The footswitch with cable and the battery charger are located outside of the sterile field.

Service Life

The handpiece is designed to function within normal specifications (not more than a 15% decline in RPM and/or magnet strength, and no discernable increase in vibration,) for a minimum of 100 autoclave cycles (134°C, 18 minutes hold). Beyond this point, the handpiece speed and power may begin to decline. The user must visually inspect the handpiece and cable, angled adaptors, and sterilization tray after each use. Replace components that appear to be chipped or damaged. Test the system for Essential Performance prior to each use, as identified in the quick start up guide on page 4. Return for service in the event of a performance failure. **Items to be returned must be reprocessed in accordance with APPENDIX A.** With proper charging and care, the rechargeable 1.2 volt NiMH batteries may be used for up to one year, after initial use.

Indications For Use:

The DragonFly™ Surgical Drill System has been designed for the light drilling of bones as part of surgical operations such as stapedotomy or ossiculoplasty.

SUBSTANTIAL EQUIVALENCE DISCUSSION

Predicate Devices: The primary predicate device is the BienAire Drill. A secondary predicate device is the Skeeter Drill. The Skeeter Drill is listed as a secondary predicate because it features equivalent Indications for Use Statement, size, control/power supply, and bur offerings.

Summary of Technological Characteristics:

COMPARISON OF FEATURES OF CANDIDATE DEVICE VERSUS PREDICATE DEVICE			
	Predicate Devices		Candidate Device
Characteristic	Skeeter Ultra-Lite Oto-tool Drill Medtronic Xomed, Inc. (Accessory of K041523)	OSSEOSTAP Microdrill Bien-Air Surgery SA K143492	DragonFly™ Surgical Drill System Candidate Device
1. Intended Use	Intended for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck, and otoneurological surgery.	Intended for the light drilling of bones as part of surgical operations such as stapedotomy or ossiculoplasty.	The DragonFly™ Surgical Drill System has been designed for the light drilling of bones as part of surgical operations such as stapedotomy or ossiculoplasty.
2. Control Unit	Foot pedal	Foot pedal	Foot pedal
3. Energy Source	Electrical (batteries)	Electrical (batteries)	Electrical (batteries)
4. Rotation Speed	Max. 12,000 rpm	Max. 12,000 rpm	Max. 9,800 rpm (Note 1)
5. Steam Autoclavable Handpieces	Yes	Yes	Yes
6. Direct Patient Contact Materials	Stainless Steel, diamond, and medical polymer	Stainless Steel, diamond, and carbide	Stainless Steel, diamond, and medical polymer (Note 2)
7. Burs Biocompatible	Yes	Yes	Yes
8. Chucking Mechanism	Mechanical Latch	Mechanical Latch	Magnetic Latch (Note 3)
9. Bur Drive Mechanism	Mechanical Drive	Mechanical Drive	Magnetic Drive (Note 4)
10. Movable outer bur guard	No	No	Yes (Note 5)

Note 1: The lower RPM of DragonFly has been shown to be acceptable in temporal bone lab bench testing.

Note 2: Stainless steel, diamond, and Medical polymers used for patient contact meet the requirements as set forth in ISO 10993

Note 3: Testing has shown the following in regards to the magnetic latching mechanism.

- An average axial force of 1.1 lb. is required to remove a bur from the angled adaptor.
- A lateral force of 0.24 lbs is required to stall a 2.3mm cutting bur.
- A minimum lateral force of 1.2 lb. is required to disarticulate a bur from the angled adaptor.

Note 4: The magnetic drive is capable of transferring a minimum of .45 in-oz of torque

Note 5: No new risks have been created as a result of the movable outer bur guard

The technological characteristics of the DragonFly™ Surgical Drill System are comparable to those of the predicate devices in the following ways.

1. Intended Use – The intended use for the Osseostap Microdrill is the same as for the subject device. The intended use for the Skeeter is equivalent to the subject device.
2. Control Unit – The control unit in both predicate devices and the subject device is a foot pedal controller.
3. Energy Source – The energy source for both predicate devices and the subject device is electrical (batteries).
4. Steam Autoclavable Handpiece – Both predicate devices offer a reusable, steam autoclavable handpiece. The subject device also offers a reusable, steam autoclavable handpiece.
5. Direct Patient Contact Materials – Both predicate devices offer diamond impregnated stainless steel cutting tools. The subject device also offers diamond impregnated stainless cutting tools.
6. Biocompatibility – Both predicate devices offer biocompatible cutting tools. The subject device also offers biocompatible cutting tools.

The technological characteristics of the DragonFly™ Surgical Drill System differ from those of the predicate devices in the following ways.

1. A Magnetic Drive Mechanism is used to transfer rotational energy to the bur. The predicate devices utilize a mechanical gear for this purpose. Surgeon feedback from bench testing and use in temporal bone labs indicated that the torque was adequate for the intended use.
2. A magnetic latching mechanism in conjunction with an angled adaptor is used to hold the bur in place. The predicate devices use a mechanical latching mechanism. Surgeon feedback from bench testing and use in temporal bone labs indicated that bur stability and latching strength was adequate for the intended use.
3. A sliding bur external bur guard is utilized which provides the user with the option to shield varying amounts of the rotating bur. The predicate devices utilize a fixed external bur guard that does not shield any portion of the bur tip. Surgeon feedback from bench testing and use in temporal bone labs indicated that a sliding bur guard was desirable, safe, and adequate for the intended use.
4. The DragonFly drill has a maximum rotation speed of 9,800 rpm. The RPM for both the Skeeter and Osseotap drills is listed at 12,000 rpm. Surgeon feedback from bench testing and use in temporal bone labs indicated that the DragonFly drill speed was deemed adequate for the intended use.

Performance Data:

A. Functionality after repeated autoclave cycles

The DragonFly™ Surgical Drill System handpiece is duty rated for 100 repeated autoclave cycles. Thirteen handpieces were subjected to 270 autoclave cycles (134C, 18 minute hold, 20 minute cool down) and tested functionally at defined intervals. The first handpiece failed, due to a decline in simulated use, at 130 autoclave cycles. The last handpiece failed simulated use and RPM after 270 autoclave cycles.

1. Drill Speed in RPM

The speed of the handpiece motor, measured in rotation per minute (RPM) was consistent for all samples between autoclave cycles. The average maximum RPM for all 13 samples at t=0 was 9,535, while the average maximum RPM at t=100 was 9,563. The highest RPM achieved in testing was 9840 RPM.

2. Simulated Use

The simulated use testing of each handpiece after 100 autoclave cycles revealed no issues related to the intended performance of the DragonFly™ handpiece.

B. Usability

1. User's understanding of the IFU

Users were able to read successfully the MicroDrill IFU and successfully determine how to turn the device on and off, charge the device, assemble handpiece components, perform start-up procedures, and recognize and correctly evaluate important functional characteristics and essential performance of the device.

2. User/s ability to determine failure of essential performance by observation:

Users were able to successfully recognize failures in the essential performance of the handpiece.

3. Software detection of essential performance

The foot control software was successfully able to detect failure of essential performance, display the appropriate alarm, and shut down the system.

C. Biocompatibility

Biocompatibility of the DragonFly™ Surgical Drill System was evaluated according to ISO

10993-1. The system's burs are in direct contact with bone or tissue for a limited duration. Representative burs were tested and passed the following tests:

- ISO Intracutaneous Irritation Test
- ISO Acute Systemic Injection Test
- ISO Mem Elution L-929 Mouse Fibroblast Cells
- ISO Guinea Pig Sensitization

D. Software

The software that controls the micro-controller in the DragonFly™ Foot Pedal has been classified as a moderate level of concern in accordance with the FDA guidance Document “*Guidance for the content of premarket submissions for software contained in medical devices issued on May 11, 2005*” and Risk Class A in accordance with IEC 62366. Software verification and validation have been conducted.

E. Electrical Safety

The electrical safety of the Dragonfly™ Surgical Drill System has been certified according to IEC 60601-1

1. IEC 60601-1-2 – Medical Electrical Equipment – PART 1-2: General Requirements for Basic Safety and Essential Performance. Collateral Standard: Electromagnetic Compatibility, and
2. ANSI/AAMI ES60601-1:2005/(R) 2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012), IEC 60601-1 Edition 3.1 (2012) / EN 60601-1 (2006) + A11 + A1 + A12

F. Cleaning and Reprocessing

Cleaning validation of the DragonFly™ Surgical Drill System components has been validated by an external lab using radioactive and protein markers. Steam autoclavability including drying has also been validated by an external lab.

G. Shelf-life

The Shelf-Life of the gamma irradiated burs has been validated for a period of 3 years.

H. Bench Testing and Surgical Evaluation of Performance.

The DragonFly Surgical Drill system was tested in parallel with the predicate device Xomed Skeeter Drill to confirm that handling and bur runout were at least as good or better.

The DragonFly Surgical Drill system was tested in parallel with the predicate device OSSEOSTAP to confirm that handling and bur runout were at least as good or better.

The DragonFly Surgical Drill system was evaluated at temporal bone labs by fifteen Otologic surgeons who were familiar with and had used the predicate Xomed Skeeter drill. A variety of Otologic surgical procedures were conducted and the DragonFly Surgical Drill was deemed to be at least as good as the predicate device in regards to operation and handling, cutting performance, and precision.

A board certified otolaryngologist compared the predicate OSSEOSTAP and Skeeter drills to the DragonFly Surgical Drill by performing surgical procedures on human temporal bone. Twenty performance characteristics were scored and the total average scores compared. The DragonFly Surgical Drill System performed comparably to or better than the predicate devices and the Surgeon deemed the DragonFly Surgical Drill as suitable for its intended use.

I. Mechanical testing

- Magnetic Drive System – Magnet Selection, Testing, and Inspection.
- Magnetic Drive System – Design and Effects of Autoclave and Aging on the System.
- Mechanical Testing of Components and Component Interactions.
- Power Supply Testing
- Footswitch Testing
- Age Reliability Testing
- Handpiece Heating

Summary and Conclusions:

Based upon comparative analysis and testing the DragonFly Surgical Drill system was found to have a safety and effectiveness profile, technological characteristics, and indications for use that are similar to the predicate devices.