March 27, 2018

The Anspach Effort, Inc.
Tamara West
Sr. Regulatory Affairs Specialist
4500 Riverside Drive
Palm Beach Gardens, FL 33410

Re: K180063
Trade/Device Name: OCM-G1 Attachment
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: February 27, 2018
Received: February 28, 2018

Dear Tamara West:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180063

Device Name
Anspach OCM-G1 Attachment

Indications for Use *(Describe)*
When used with the ANSPACH® Systems, the OCM-G1 Attachment and Burr Support Sleeves are intended for cutting and shaping bone primarily in otology procedures such as cocleostomies.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

I. SUBMITTER

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Date Prepared: January 02, 2018

II. DEVICE

Trade Name: OCM-G1 Attachment

Common Name: Surgical Cutting Tools

Classification Information: 874.4250 Drill, Surgical, ENT (Electric or Pneumatic) Including Handpiece

Regulatory Class: II

Product Code: ERL

Classification panel: Ear, Nose and Throat

III. PREDICATE DEVICE

K131053 Anspach XMax Pneumatic and eMax 2 Plus Electric Systems with Otologic Attachment System (Otologic Attachment and Curved Burrs)

ANSPACH®

IV. DEVICE DESCRIPTION

The *OCM-G1 (Otologic Curved Micro) Attachment* is an accessory to the G1 electric drill system. It is a one-piece straight attachment that is manufactured from 17-4PH and 303 stainless steels (ASTM A564 and ASTM A582). The *OCM-G1 Attachment* can be connected and disconnected to the distal end of the handpiece via a locking mechanism by the user.

After the *OCM-G1 Attachment* is secured to the handpiece, it will accept and hold an OCM curved burr support sleeve assembly (previously cleared). The OCM curved burr support sleeve assembly will rotate at a speed selected by the user for cutting and shaping bone, primarily in otology procedures such as cochleostomies.

The *OCM-G1 Attachment* is provided non-sterile and is reusable.

V. INDICATIONS FOR USE

When used with the ANSPACH Systems, the OCM-G1 Attachment is intended for cutting and shaping bone primarily in otology procedures such as cochleostomies.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	OCM-G1 Attachment	**eMax 2 Plus Electric Systems with Otologic Attachment System (Otologic Attachment and Curved Burrs)**
510(k) Number	K180063	K131053
Indications for Use	When used with the ANSPACH Systems, the OCM-G1 Attachment is intended for cutting and shaping bone primarily in otology procedures such as cochleostomies.	When used with the ANSPACH Systems, the OCM Attachment and OCM Burr Support Sleeves are intended for cutting and shaping bone primarily in otology procedures such as cochleostomies.
Sterilization	Non-sterile	Non-sterile
Product Code	ERL	ERL, EQJ
Dissection Tools - NA		
Console - NA		
Handpiece - NA		
Foot Control - NA		
Attachment		
Description	Same	Straight Attachment
Locking Mechanism	Diamond Flat configuration	560 Flat configuration
Material	Same	Stainless Steel
Length	2.5mm	2.6mm
Knurl sleeve	Yes	No
Connection to	Same	Quick Disconnect

handpiece		
Labeling	Same	Non-sterile

The predicate OCM Attachment (K131053) is an accessory to an electric/pneumatic handpiece that utilizes the 560 Flat configuration locking mechanism. A minor design change was made to the locking mechanism of the predicate attachment (K131053) modifying it from connecting to a handpiece with a 560 Flat locking configuration to connecting to a handpiece with a Diamond Flat configuration. To allow for ease of connection/disconnection with the handpiece, a knurl sleeve was added to the proximal end of the proposed *OCM-G1 Attachment* unlike the predicate (K131053) where the knurl sleeve was located on the handpiece.

The proposed *OCM-G1 Attachment* remains similar to the predicate attachment (K131053) in terms of operating principles, where it holds and secures a curved burr support sleeve assembly intended for cutting and shaping bone primarily in otology procedures such as cochleostomies. The indications for use, material and manufacturing remain similar to the predicate attachment.

In addition, the *OCM-G1 Attachment* will utilize the same OCM Curved Burr Support Sleeves as the predicate.

The technological characteristics of the proposed *OCM-G1 Attachment* are similar to those of the predicate (K131053) device in the following ways:

- Both attachments use a patented locking mechanism (input shafts) to secure to handpiece
- Both attachments are compatible with the same OCM curved burr support sleeve assembly currently on the market
- Both attachments by design have a straight outer metal cover with internal components
- Both attachments are non-sterile reusable, steam autoclavable devices

The following technological differences between the proposed and predicate (K131053) device were considered in relation to the substantial equivalence determination:

- Use of a Diamond Flat configuration on the proposed *OCM-G1 Attachment* for locking mechanism opposed to 560 Flat configuration. The Diamond Flat configuration allows the proposed *OCM-G1 Attachment* to be compatible with the G1 handpiece only. The predicate (K131053) is compatible with handpieces compatible with the 560 Flat configuration.
- The proposed *OCM-G1 Attachment* is compatible with an electric powered drill system while the predicate (K131053) is compatible with various electric and pneumatic powered drill systems. There is no change to the performance of the attachment as compared to the predicate (K131053).
- A knurl sleeve was incorporated on the proximal end of the *OCM-G1 Attachment* for ease of use and which allows the attachment to be removed from the handpiece

using one less step than the predicate. For the proposed *OCM-G1 Attachment,* the act of twisting the attachment locks in the dissection tools or burr on handpiece, whereas on the predicate (K131053) retracting (and releasing) the disconnect sleeve allows the dissection tool or burr to be installed/removed.

- Total length of the proposed *OCM-G1 Attachment* is 2.5mm opposed to 2.6mm of predicate (K131053).

The proposed changes to the *OCM-G1 Attachment* have no impact on the safety and effectiveness of the device or its ability to perform as intended.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing:
The *OCM-G1 Attachment* does not have direct or indirect patient contact, same as the predicate. A biocompatibility evaluation was conducted for the *OCM-G1 Attachment* per the FDA guidance document Use of International Standard ISO 10993-1. "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

The *OCM-G1 Attachment* is manufactured and packaged in the same manner with identical material as the predicate device (K131053). No new or additional processing steps were introduced; therefore, biocompatibility requirements have been met.

Design Control Activities:
The following verification tests were performed to demonstrate that the device meets the performance requirements under its indications for use conditions.

- Locking feature compatibility
- Temperature
- Disconnect without tools
- System functionality

The above tests demonstrate proper functionality, compatibility, safe external temperatures, and the ability to connect and disconnect without the use of tools, the same as the predicate (K131053). A simulated use study demonstrated the *OCM-G1 Attachment* and curved cutting burrs perform as intended in cutting and shaping bone properly in the same manner as the predicate (K131053).

Cleaning and Reprocessing:
The *OCM-G1 Attachment* was assessed to determine whether or not current validations for clinical processing and steam sterilization are capable of producing a sterility assurance

level (SAL) of 10^{-6}. Overall, the proposed *OCM-G1 Attachment* device characteristics would be equal or less of a challenge to sterilize than the currently validated "worst case" with the ability to be cleaned and sterilized effectively without adverse effects, same as the predicate (K131053).

Clinical Testing:
No clinical testing was necessary for a determination of substantial equivalence.

VII. CONCLUSIONS

The *OCM-G1 Attachment* described in this submission has the same intended use, general design, material, technological characteristics, and principles of operation as the predicate device (K131053). The introduction of the attachment does not raise any new issues of safety or efficacy and was found to be substantially equivalent to the predicate (K131053) device.

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