510(k) Summary

The summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93.

JAN 10 2014

Submitter	The Anspach Effort, Inc. 4500 Riverside Drive Palm Beach Gardens, FL 33410
Official Correspondent	Jeannette G. Dailey Regulatory Affairs Manager Tel. 561-494-3710 Fax. 561-625-9110 Email: dailey.jeannette@synthes.com
Date Prepared	November 22, 2013
Device Name	Anspach eG1 High Speed Electric System
Common Name	Electric Drill Motor System
Classifications	Class II Neurological Devices 21 CFR § 882.4360 HBC Class II Ear, Nose and Throat Devices 21 CFR § 874.4250 ERL
Predicate Devices	eMax Drill System The Anspach Effort, Inc. K011444 HBC, ERL
Device Description	The Anspach eG1 High Speed System, which consists of a control console, handpiece, and various attachments, is an electrically powered surgical drill that handles a range of surgical procedures ranging from power-demanding applications to delicate dissection.
Indications for Use	The Anspach eG1 High Speed Electric System is intended for cutting and shaping bone including spine and cranium.

Technological Characteristics	The Anspach eG1 High Speed Electric System and attachments are provided non-sterile, reusable. The Anspach eG1 High Speed Electric System and attachments are designed utilizing the same materials and contains features and functions which are similar to the predicate devices.
Performance Testing	Design verification was conducted on the proposed design changes of the Anspach eG1 High Speed Electric System and attachments. These tests include a functional approach that challenged the design output against the design requirements. The tests verified established physical characteristics, functional requirements and performance standards.
Conclusion	Based on the testing, risk analysis and comparison to the predicate devices, the Anspach eG1 High Speed Electric System and attachments described in this submission perform as intended and raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

The Anspach Effort, Inc.
Ms. Jeannette G. Dailey
Regulatory Affairs Manager
4500 Riverside Drive
Palm Beach Gardens, Florida 33410

January 10, 2014

Re: K133604
Trade/Device Name: Anspach eG1 High Speed Electric System Dissection Tools
Regulation Number: 21 CFR 882.4360
Regulation Name: Electric cranial drill motor
Regulatory Class: Class II
Product Code: HBC, ERL
Dated: December 12, 2013
Received: December 13, 2013

Dear Ms. Dailey:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
For Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133604

Device Name: Anspach eG1 High Speed Electric System

Indications for Use:

The Anspach eG1 High Speed Electric System is intended for cutting and shaping bone including spine and cranium.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A Digitally signed by Long H. Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300349056 Date: 2014.01.10 12:09:02 -05'00' for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K133604