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

December 16, 2015

Denali Corporation
Jan G. Stannard
President
134 Old Washington Street
Hanover, Massachusetts 02339

Re: K152322
Trade/Device Name: Resolve 2.0
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity varnish
Regulatory Class: Class II
Product Code: LBH
Dated: November 4, 2015
Received: November 9, 2015

Dear Ms. Jan G. Stannard:

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" (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 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,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (k) Number
152322

Device Name

Resolve 2.0

Indications for Use:

Resolve 2.0 is recommended for use on dental restorations, external to the mouth, prior to insertion into the mouth. After applying Resolve 2.0 to cleanse the restoration, the surface of the restoration should be washed thoroughly with water, and then air dried before placement in the mouth.

For Use only by a Licensed Dentist. Rx Use Only. Non-sterile.

Please do not write below this line. Continue on another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

☒ Prescription Use (Per 21 CFR 801.109) or ☐ Over-The-Counter Use

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510 (k) Summary

December 10, 2015

ADDRESS
DENALI CORPORATION
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OWNER/CONTACT PERSON
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TRADE NAME
Resolve 2.0

COMMON NAME
External Cleansing Solution, Cavity Varnish

CLASSIFICATION NAME
Cavity Varnish, Class II (21 CFR 872.3260, Product Code PME)

REGISTRATION
3006367836

PRIMARY PREDICATE DEVICE
Consepsis, Ultradent Products (k925375)

EQUIVALENCE
The predicate product has been found substantially equivalent under the 510(k) premarket notification process as Class II Dental Devices under CFR PME 872.3260.

DEVICE DESCRIPTION
Resolve 2.0 is a thin, non-alcohol based gel containing chlorhexidine gluconate. This thin gel because of its water solubility, abrasive action and low viscosity when applied to dental restorations, acts as a cleaning agent. This gel is provided in easy to use syringes and floc-tipped applicator tips to precisely deliver the gel to the intended areas.

For Use only by a Licensed Dentist. Rx Use Only. Non-sterile.

INTENDED USE
Resolve 2.0 is recommended for use on dental restorations, external to the mouth, prior to insertion into the mouth. After applying Resolve 2.0 to cleanse the restoration, the surface of the restoration should be washed thoroughly with water, and then air dried before placement in the mouth.

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510 (k) Summary *(continued)*

TECHNOLOGICAL CHARACTERISTICS SUMMARY

Resolve 2.0 has the same technological characteristics as Consepsis including: design, composition, biocompatibility, performance, ageing, intended use, physical characteristics, including pH, shelf life, water solubility, and cleansing activity, as summarized in the Table below.

PROPERTY	Resolve 2.0	Consepsis*
Cleansing Activity	Yes	Yes
Contains Chlorhexidine gluconate	Yes	Yes
Water Soluble	Yes	Yes
pH	6	6
Contains silicate (sand)	Yes	Yes
Consistency	Thin liquid	Thin liquid
Pigmented	Yes	Yes
Ageing/Shelf Life Test - Accelerated Ageing at 37'C	PASS, 2.0+ year shelf life established	PASS, 2.0+ year shelf life established

BIOCOMPATIBILITY

Resolve 2.0 was found to be biocompatible, and is consistent in formulation to Consepsis, in its limited intended uses, biocompatibility, and properties. Resolve 2.0 was evaluated per ISO 10993-5 "Biological Evaluation of Medical Devices". Resolve 2.0 and Consepsis according to ISO 10993-5 both had cytotoxicity values of "Moderate", exhibiting a reactivity zone extending from the specimen up to 1.0 cm. According to these results Resolve 2.0 was found to be equivalent in biocompatibilty compared to the predicate product Consepsis.

SUBSTANTIAL EQUIVALENCE DETERMINATION AND SUMMARY

Resolve 2.0 is substantially equivalent in design, composition, biocompatibility according to ISO 10993, performance, ageing, limited intended uses, and safety and effectiveness to Consepsis. This assessment is based upon a comparison of the composition and physical properties of water solubility, pH, shelf-life and cleansing activity to Consepsis, as well as Biocompatibility evaluation. The results of these tests are consistent with values of the predicate product.

CONCLUSIONS

Resolve 2.0 has been found to be substantially equivalent in design, composition, ageing, biocompatibility, performance, with limited intended uses to Consepsis.