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

September 22, 2014

Nanova Biomaterials, Incorporated
Mr. Andrew Ritts
Senior Scientist
3806 Mojave Court
Columbia, MO 65202

Re: K140349
Trade/Device Name: StarBright™ 5% Sodium Fluoride Varnish
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: August 1, 2014
Received: August 8, 2014

Dear Mr. Ritts:

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,

Mary S. Runner -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

Section 4. Indications for Use Statement

(As Required by 21 CFR 807.87(e))

510(k) Number (if known): K140349

Device Name: **StarBright™** 5% Sodium Fluoride Varnish

Indications For Use:

StarBright™ 5% Sodium Fluoride Varnish is a fluoride containing preparation for use as a cavity varnish and for the treatment of dentin hypersensitivity.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5. 510(k) Summary

1) Submitted By:

Nanova Biomaterials, Inc
3806 Mojave Ct.
Columbia, MO 65202
USA
(573)-875-6682

Contact Person: Andrew Ritts Phone: (573) 823-3114
Secondary Contact: Kathryn Giddens Phone: (573) 864-1701

2) Establishment Registration No.: NA

3) Date Prepared: July 1st, 2014

4) Device Trade Name: **StarBright™** 5% Sodium Fluoride Varnish

5) Device Common Name: Dental Varnish

6) Device Classification Name: Cavity Varnish

7) Classification Panel: Class II

8) Device Class: Dental

9) Predicated Devices:
StarBright™ 5% Sodium Fluoride Varnish is believed to be substantially equivalent to the following marketed products:

510(k) Number	Name of Device	Product Code	Company
K961893	Duraflor ®	LBH	Pharmascience, Inc.
K092141	3M Vanish	LBH	3M ESPE
K103160	Nupro Model 13016901	LBH	Cao Group, Inc.
K132109	Enamelast	LBH	Ultradent Products, Inc

10) Indication for Use:

StarBright™ 5% Sodium Fluoride Varnish is a fluoride containing preparation for use as a cavity varnish and for the treatment of dentin hypersensitivity.

Section 5. 510(k) Summary - Cont.

11) Device Description:

StarBright™ 5% Sodium Fluoride Varnish is a rosin based 5% sodium fluoride varnish. This device is available in tray form unit doses of 0.25 and 0.40 mL.

Fluoride ions within **StarBright™** 5% Sodium Fluoride Varnish may react with calcium and phosphate ions in saliva to form crystals in exposed dentin tubules, such as in exposed root surfaces, leading to protection by blocking external stimuli thereby reducing hypersensitivity.

12) Substantial Equivalence:

The document, "Guidance on the CDRH Premarket Notification Review Program, 6/30/86 (K86-3)" was used to determine substantial equivalence:

a) The applicant device has the same intended use as the 510(k) cleared predicates listed above.

b) The technological characteristics of this product are believed to be substantially equivalent as those for the predicate devices and other rosin based products currently on the market. This device and its predicates are substantially equivalent in composition and material. **StarBright™** 5% Sodium Fluoride Varnish is a paste formulation delivered in unit dose packaging and applied on the tooth surface with a disposable brush, similar to several 510(k) cleared products already on the market.

13). Non-clinical performance testing:

Non-clinical performance testing on **StarBright™** including fluoride release and tubule occlusion support substantial equivalence to the listed predicates. Biological testing included cytotoxicity, sensitization, and irritation. The conclusions drawn from the nonclinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.

14). Clinical performance testing:

Clinical performance data was not included.

Section 5. 510(k) Summary - Cont.

Conclusion:

Nanova Biomaterials Inc. believes that StarBrightTM 5% Sodium Fluoride varnish is substantially equivalent to the currently legally marketed products. It does not introduce new indications for use, has similar technological characteristics and does not introduce new potential hazards or safety risks.