February 18, 2020

Scientific Pharmaceuticals
Thomas Kelly
Regulatory Affairs/Quality Assurance Manager
3221 Producer Way
Pomona, California 91768

Re: K192381
Trade/Device Name: DFV Desensitizing Varnish-Strawberry Flavor, DFV Desensitizing Varnish-Bubblegum (Tutti-Fruity) Flavor, DFV Desensitizing Varnish-Spearmint Flavor, DFV Desensitizing Varnish-Chocolate Flavor, DFV Desensitizing Varnish-Marshmallow Flavor
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: LBH
Dated: November 20, 2019
Received: November 20, 2019

Dear Thomas Kelly:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K192381

Device Name
DFV Desensitizing Varnish

Indications for Use *(Describe)*

SciPharm's DFV Desensitizing Varnish is a fluoride-containing resin preparation for the treatment of dentinal hypersensitivity and for the reduction of post-operative sensitivity.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Scientific Pharmaceuticals
3221 Producer Way
Pomona, CA 91768

510(k) Summary – K192381

510(k) Submission:	Traditional
Device Type:	Varnish, Cavity
Submitter:	Scientific Pharmaceuticals, Inc. 3221 Producer Way Pomona, CA 91768
Contact Person:	Thomas Kelly Regulatory Affairs/Quality Assurance Manager Regulatory@scipharm.com Telephone: 909-595-9922 ext. 237
Alternate Contact Person:	David Butler President Dave@scipharm.com Telephone: 909-595-9922 ext. 225
Date:	February 18, 2020
Confidentiality:	According to 21 CFR 807.95
Trade Name:	Sci-Pharm DFV Desensitizing Varnish
Common Name:	Cavity Varnish or Topical Varnish
Classification Name and References:	Cavity Varnish 21CFR 872.3260
Product Code:	LBH
Classification Panel:	Dental
Classification:	Medical Device, Class II

Scientific Pharmaceuticals
3221 Producer Way
Pomona, CA 91768

Purpose and Description:

SciPharm's DFV Desensitizing Varnish is a device that consists of a synthetic compound from a natural rosin that is intended to coat a prepared tooth cavity prior to the insertion of a restorative material by forming a film that facilitates occlusion of compromised surfaces, including open dentinal tubules. DFV Desensitizing Varnish and the predicate device consist of a viscous liquid that can be applied to the teeth using a brush or similar applicator. The purpose of the 5% sodium fluoride as the source of fluoride ions for the formation of calcium fluoride, and along with the rosin, occludes the dentin tubules. Both use denatured alcohol (ethanol) as a significant component, providing fluidity for application and to promote quick drying on the tooth surface.

SciPharm's DFV Desensitizing Varnish is a topically applied, flavored (Strawberry, Bubblegum, Spearmint, Chocolate, and Marshmallow) topical varnish containing sodium fluoride on a synthetic rosin based preparation from a natural rosin. Only a professional clinician may apply DFV Desensitizing Varnish. The varnish and applicator are packaged in a thermoformed PET/PVC opaque unit dose tray, and sealed with foil.

The technological difference between DFV Desensitizing Varnish and the other six (6) varnishes that Scientific Pharmaceutical's manufactures is the formulation of components. The components are commonly used in the dental materials industry. The DFV Desensitizing Varnish uses a synthetic resin as the base material instead of the natural rosin used in other formulations. This synthetic rosin is the same used in the predicate device. DFV Desensitizing Varnish also includes additional base material, sweeteners, bitterness blockers, and flavoring agents.

The device is intended to prevent the penetration of restorative materials, such as amalgam, into dental tissue.

Scientific Pharmaceuticals
3221 Producer Way
Pomona, CA 91768

Chemical Composition:

	Raw Material (Ingredient)	Purpose of Ingredient	Concentration of Ingredient
1.	Purified Rosin	Film Former	45.0% - 75.0%
2.	Polyamide	Film Former	10.0% - 25.0%
3.	Ethanol, 200 Proof	Solvent, Surface Wettability	10.0% - 25.0%
4.	Sodium Fluoride	Reduce Tooth Decay	4.50% - 5.50%
5.	Carbamide Peroxide	Whitening Agent for color stability	0.25% - 5.0%
6.	Xylitol	Sweetener and stimulates saliva flow	0.5% - 4.0%
7.	Sucralose	Sweetener	0.25% - 5.0%
8.	Bitter Blocker	Flavoring Agent	0.10% - 3.00 %
9.	Silica Filler	Thickener	1.0% - 5.0%
10.	Flavorants (Strawberry, Bubblegum, Spearmint, Chocolate, & Marshmallow)	Flavoring Agent	0.25% - 10.0%

Contraindications: Patients allergic, or hypersensitive, to natural resin or colophony (kolophonium or resembling agents) should avoid the use of this product. In case of an adverse reaction, the varnish may be removed by brushing with a soft toothbrush and flossing, followed by rinsing with warm water. Direct ingestion should be avoided. Dyspnea, (difficult or labored breathing) associated with asthmatic children, has been reported in rare cases. Patients with sensitive digestive systems may experience nausea, usually after a prolonged treatment. Patients with stomatitis or ulcerative gingivitis should avoid this product.

Primary Predicate Device: Young Dental Manufacturing: *Oral-B 5% Sodium Fluoride Varnish* (K153334).

Reference Device: 3M: *Vanish 5% Sodium Fluoride White Varnish* (K090519)

Accessories(s): Unit dose container, Nylon Brushes for application, mixing well.

Scientific Pharmaceuticals
3221 Producer Way
Pomona, CA 91768

Comparison to Predicate Device

	DFV Desensitizing Varnish	Primary Predicate Device Oral-B 5% Sodium Fluoride Varnish	Reference Device Vanish Varnish
	-------	K153334	K090519
Indications for Use (abbreviated)	Treatment of dental hypersensitivity and reduction of post-operative sensitivity	Treatment of dental hypersensitivity and reduction of post-operative sensitivity	Treatment of dental hypersensitivity and reduction of post-operative sensitivity
Contraindications	Hypersensitivity to colophony should avoid this product, as well as patients with ulcerative gingivitis and stomatitis	Ulcerative gingivitis and stomatitis	Hypersensitivity to colophony should avoid this product, as well as patients with ulcerative gingivitis and stomatitis
Mode of Action	Dentin Tubule Occlusion	Dentin Tubule Occlusion	Dentin Tubule Occlusion
Method of Application	Application of a thin coat of varnish of varnish on tooth surfaces only by a professional. Not for home use.	Application of a thin coat of varnish of varnish on tooth surfaces.	Application of a thin coat of varnish of varnish on tooth surfaces only by a professional. Not for home use.
Percentage of Sodium Fluoride	5%	5%	5%
Packaging	Varnish and applicator brush placed in a thermoformed PET/PVC opaque unit dose tray and closed with a peelable foil seal.	Varnish and applicator brush placed in a molded opaque acclar tray and closed with a foil seal.	Varnish and applicator brush placed in a molded opaque tray and closed with a foil seal.
Unit Package	0.4 mL	0.4 mL	0.5 mL
Basic Composition	Synthetic Rosin	Synthetic Rosin	Synthetic Rosin

Technological Characteristics: The basic composition, fundamental technology, and intended use of DFV Desensitizing Varnish is substantially equivalent to the predicate device and comparable to devices that have been on the market for many decades. These products use components used in the dental industry such as resins, rosins, modified rosins hydroxypropyl cellulose, polyurethane, methacrylates, polyethylene glycol, amides, dimethacrylates, and other film forming ingredients to cover dentinal tubules, which provide relief from dentinal

hypersensitivity. DFV Desensitizing Varnish is a varnish that contains sodium fluoride, like all of the others, and contains rosin that provides immediate and sustained relief of dental pain or sensitivity. The immediate relief of hypersensitivity is achieved by the hardened resin films that forms immediately after application and occludes the dentin tubules.

Biocompatibility Tests:

The chemical components in Sci-Pharm's DFV Desensitizing Varnish have been used in a variety of predicate devices. Rosin and other rosin derivatives are used as adhesive agents in approved dental varnishes.

Biocompatibility testing is an essential element of developing a medical device. Each medical device used in dentistry shall be subjected to a structured biological evaluation program within a risk management process. In order to comply with the requirements, DFV Desensitizing Varnish was tested for cytotoxicity and to provide evidence that the formula blocks dentinal tubules.

Cytotoxicity followed the procedure outlined in ISO 10993-5 and ISO 7405, where a smear was extracted in Minimal Essential Medium (MEM) with 10% Fetal Bovine Serum for 24 hours at 37°C. Then L929 cells were exposed to the extracts and the viability of the cells were measured by their ability to uptake a vital dye. The viability percentage of the cells exposed to the extracts from DFV Desensitizing Varnish was 11%, which is below the 70% (Toxicon Report 17-04113-G1). This value is expected as it contains significant ethanol, so an additional study was conducted using an approved dental varnish that is similar, and currently being used on the market. The predicate product is another dental varnish already on the market and compared with the same methodology to determine cytotoxicity from DFV Desensitizing varnish. The viability percentage of the cells exposed to the extracts from an equivalent device was also 11%, which is also below the 70% (Toxicon Report 18-00602-G1). The cytotoxicity for both varnishes are the same, indicating that there is no difference. Based on the chemical content, the residual ethanol will disrupt cellular integrity, the sodium fluoride is a bacterial growth inhibitor, which can also affect the viability of the cells, as can the carbamide peroxide. All of these chemicals had an effect that contributed towards the low cellular viability result, but since these are the very same chemicals used for all approved dental varnishes

Scientific Pharmaceuticals
3221 Producer Way
Pomona, CA 91768

currently on the market, then they are found acceptable. Additional testing can be requested, but the results will be the same due to the ethanol, not the flavor.

The second test is where dentin is exposed to the varnish and viewed under SEM to verify that the varnish blocks dentinal tubulae. There were two varnishes evaluated, Sci-Pharm's DFV Desensitizing Varnish and an equivalent predicate varnish. Disk-shaped human dentine specimens had the varnishes applied separately using a plastic brush and a single stroke. The surfaces were imaged using reflection optical microscopy (ROM), allowing the identification morphology of the specimen surfaces without the dehydration effects. Then the top surface of the sectioned specimens were examined using a scanning electron microscope (SEM). The ROM images demonstrated a typical granular appearance with dentinal tubule orifices closed by smear plugs. Both varnishes tested showed highly smooth material layer covering all of the dentine and when evaluated by SEM, Sci-Pharm's DFV Desensitizing Varnish remained smooth with minimal surface defects while the other varnish showed subsurface porosity and heterogeneity. The conclusion was that Sci-Pharm's DFV Desensitizing Varnish demonstrated a thick uniform film with fewer defects and protrusions than the competitors varnish. Additional testing is not necessary as the benefits are from sodium fluoride and the rosin mixture, not the flavors.

Physical Tests:

Test	Proposed DFV Desensitizing Varnish	Equivalent Varnish
Contamination	No Foreign Particles	No Foreign Particles
Color	Match Standard	Match Standard
Odor	Match Standard	Match Standard
Viscosity	4500 – 6500 cps	7000 – 8500 cps
Non-Pyrolizable %	7.5% - 8.7%	8.4% - 9.5%
Fluoride Content	4.5% - 5.5% NaF (2.0% - 2.5% F)	4.5% - 5.5% NaF (2.0% - 2.5% F)

Shelf Life 2 Years

Scientific Pharmaceuticals
3221 Producer Way
Pomona, CA 91768

Shelf Life was established following Sci-Pharm's internal procedure, EX-06, where the product being tested is analyzed during intervals within the shelf life, such as Time 0, Time 6 months, Time 12 months, Time 18 months, etc., and continued for up to 4 years. The product is evaluated for any changes that may occur over time. Testing is performed on contamination, color, viscosity, fluoride content, non-pyrolizable percentage, and odor. Color changes may occur over time, but since a small thin layer that is washed off within hours, the color change in the product is not substantial. Report 2019-R-012 provides evidence that the product is stable for at least 24 months.

Substantial Equivalence:

In summary, this submission demonstrates that Sci-Pharm's DFV Desensitizing Varnish is substantially equivalent in safety and effectiveness, and performs equivalently or better than the identified primary predicate device and the reference device varnishes for their intended use. Device is biocompatible when used as directed by dental professionals per ISO 10993-1. DFV Desensitizing Varnish does not introduce any new indications for use or potential hazards.