September 13, 2019

Johnson & Johnson Surgical Vision, Inc.
Silvia Jiang-Hughes, Ph.D.
Project Manager, Regulatory Affairs
1700 East Saint Andrew Place
Santa Ana, California 92705

Re: K191949
Trade/Device Name: UNFOLDER Vitan™ Inserter, Model DK9000
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: July 19, 2019
Received: July 22, 2019

Dear Dr. Jiang-Hughes:

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,

for Bennett Walker, Ph.D.
Acting Assistant Director
DHT1A: Division of Ophthalmic 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)*
K191949

Device Name
UNFOLDER Vitan™ Inserter, Model DK9000

Indications for Use *(Describe)*
The UNFOLDER Vitan™ Inserter, Model DK9000, is used in combination with the SmartLOAD™ Delivery Technology to fold and assist in inserting Johnson & Johnson Surgical Vision, Inc. Acrylic 1-piece intraocular lenses, ONLY into the capsular bag.

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.

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6. 510(K) SUMMARY

6.1. Applicant Information

This 510(k) summary is being submitted in accordance with the Medical Device Amendments of 1976, the requirements of the Safe Medical Device Act (SMDA) of 1990 and 21 CFR 807.92.

Submitter Information:	Johnson & Johnson Surgical Vision, Inc. 1700 E. St. Andrew Place Santa Ana, CA 92799-5162, USA
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	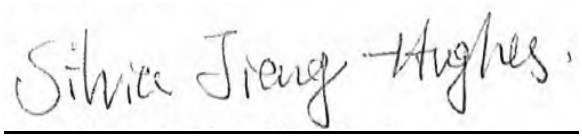
Date of 510(k) Summary Preparation	July 18, 2019

6.2. Subject Device

Trade / Proprietary Name:	UNFOLDER Vitan™ Inserter, DK9000 (Previously referred as DK7799)
Common Name:	Intraocular Lens Guide
Classification Name:	Intraocular Lens Guide per 21 CFR 886.4300
Product Code:	MSS
Regulatory Class:	Class I

6.3. Substantial Equivalence Summary

The device to which substantial equivalence is claimed for the UNFOLDER Vitan™ Inserter, Model DK9000, is listed in **Table 6-1** below:

Table 6-1: Predicate Devices to Which Substantial Equivalence is Claimed for the UNFOLDER Vitan™ Inserter, DK9000.

510(k) Number	Date of FDA Clearance / 510(k) Note to File	Predicate Device	510(k) Holder
K081382	October 23, 2008	Duckworth & Kent Ltd., Injector, Model DK7786	Duckworth and Kent Ltd.

6.4. Device Description

The UNFOLDER Vitan™ Inserter, Model DK9000, is an autoclavable, reusable titanium intraocular lens (IOL) inserter or handpiece that is designed for use in combination with the SmartLOAD™ Delivery Technology (P980040/S095) to fold and assist in the insertion of a J&J Vision acrylic one-piece IOL into the eye following cataract extraction. The IOL is provided preloaded in the disposable polypropylene cartridge and is snapped into the inserter. The screw plunger advances the IOL through the cartridge, which folds the IOL and advances it into the eye. The SmartLOAD™ Delivery Technology cartridge is designed to eliminate the need for the IOL to be loaded into the cartridge to provide a sterile, controlled, and convenient method of efficiently delivering J&J Vision acrylic one-piece lenses into the eye during cataract surgery.

6.5. Indications for Use

The following is the Indications for Use statement for the UNFOLDER Vitan™ Inserter, DK9000:

> *The UNFOLDER Vitan™ Inserter, DK9000, is used in combination with the SmartLOAD™ Delivery Technology to fold and assist in inserting Johnson & Johnson Surgical Vision, Inc. Acrylic 1-piece intraocular lenses, ONLY into the capsular bag.*

The Indications for Use statement of the subject device is similar or equivalent to the predicate device.

The IOLs for use with Model DK9000 include J&J Vision's one-piece monofocal IOLs made from either the SENSAR® soft acrylic material or the SENSAR® soft acrylic material with a proprietary violet light-filtering chromophore that reduces transmittance of violet wavelengths. They are preloaded with the SmartLOAD™ Delivery Technology and identical to the IOLs approved in the wheelcase or daisywheel package configuration. They share the same general optical and mechanical designs, with differences in the anterior surface having either spherical or aspheric optics. The differences in the lens models validated for use with the SmartLOAD™ Delivery Technology and UNFOLDER Vitan™ Inserter do not affect the safety and effectiveness of the UNFOLDER Vitan™ Inserter.

6.6. Technological Characteristics of the Device

The UNFOLDER Vitan™ Inserter, Model DK9000, is equivalent to its predicate device, the Duckworth & Kent Ltd. (D&K) Injector, Model DK7786, in terms of its intended use, operating principle, technological characteristics, component materials, manufacturing process, biocompatibility, steam sterilization method, performance, and FDA-recognized standards used for performance testing.

The differences between the UNFOLDER Vitan™ Inserter, Model DK9000 and the predicate device Model DK7786 consist of the following aspects:

- The subject device Model DK9000 is designed to be attached to the SmartLOAD™ Delivery Technology (P980040/S095), in which IOL is preloaded in the cartridge to provide a sterile, controlled, and convenient method of efficiently delivering the IOLs into the eye during cataract surgery. The predicate device Model DK7786 can only be used in combination with 1VIPR30 cartridge (K143434), The loading area difference between Model DK9000 and Model DK7786 is the orientation of the snap feature on the injector bodies. Model DK7786 engages with the wings of the 1VIPR30 cartridge while Model DK9000 engages with the body of the SmartLOAD™ Delivery Technology.

- For easy identification, the subject device Model DK9000 is colored with blue titanium through anodizing process, whereas the predicate device model DK7786 is with gold color.

- The subject device Model DK9000 can be operated by twisting the plunger to deliver the lenses in the capsular bag, however, the predicate device Model DK7786 is operated by pushing the plunger.

These differences have been assessed in performance testing of the subject device**.** Despite these differences, the other user steps for operating the device, such as cleaning and sterilization are generally the same for the subject device and the predicate device.

6.7. Summary of Non-Clinical Tests

The UNFOLDER Vitan™ Inserter, Model DK9000, has undergone testing and complies with applicable standards. A reprocessing study was conducted on the UNFOLDER Vitan™ Inserter to verify that the inserters can withstand repeated clinical re-processing cycles (CRC) without losing any of its functional properties. Performance of the UNFOLDER Vitan™ Inserters in conjunction with the SmartLOAD™ Delivery Technology were evaluated with respect to inserter compatibility, functionality, and reusability. Upon completion of the five hundred (500) CRC and functional verification, the devices remained intact and successfully delivered IOLs per the Directions for Use (DFU), with no indications on the degradation of the functional surfaces, mating surfaces,

identification marks, thread forms or functional capability. In addition, functional delivery testing was performed on the UNFOLDER Vitan™ Inserter with the SmartLOAD™ Delivery Technology in accordance with Section 5 of ISO 11979-3: 2012. All tested IOLs under simulated surgical manipulation passed all acceptance criteria for post-delivery dioptric power, image quality, overall diameter, sagitta, and surface and bulk homogeneity. The overall results demonstrated substantial equivalence between the subject device and the predicate devices with respect to functional performance. All performance testing of the UNFOLDER Vitan™ Inserter demonstrate that the device is as safe and effective as the respective predicate devices.

6.8. Summary of Clinical Tests

No clinical studies were deemed necessary to determine the safety and effectiveness of the UNFOLDER Vitan™ Inserter, Model DK9000.

6.9. Conclusions

The technological characteristics that determine the functionality and performance of the subject device, the UNFOLDER Vitan™ Inserter, Model DK9000, is substantially equivalent to the D&K Injector, Model DK7786, which is included in the scope of premarket notification K081382. The UNFOLDER Vitan™ Inserter will be manufactured in compliance with FDA and ISO quality system requirements. The data from the non-clinical tests demonstrate that the safety and effectiveness profile of the subject device is equivalent to that of the legally marketed predicate devices. Verification and validation testing demonstrate that the functional requirements and product specifications will be met prior to commercial release.