December 23, 2022

Visant Medical, Inc.
% Lee Kramm, M.D., M.S.E.
President, Chief Strategist and Medical Officer
Regulatory Pathways Group Inc.
340 S. Lemon Ave
Walnut, CA 91789-2706

Re: K222164
Trade/Device Name: Visant Medical Canalicular Plug
Regulatory Class: Unclassified
Product Code: LZU
Dated: November 23, 2022
Received: November 25, 2022

Dear Lee Kramm, M.D., M.S.E.:

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 titled, "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,

J Angelo Green -S

J. Angelo Green, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222164

Device Name
Visant Medical Canalicular Plug

Indications for Use *(Describe)*

The Visant Medical Canalicular Plug is intended to block tear drainage by occlusion of the canalicular system. It is indicated for use, for up to 6 months, in patients experiencing dry eye symptoms.

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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I. SUBMITTER

APPLICANT: Visant Medical, Inc.
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OFFICIAL CORRESPONDENT: Lee Kramm
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DATE SUMMARY PREPARED: December 22, 2022

II. DEVICE

TRADE NAME: Visant Medical Canalicular Plug

COMMON NAME: Canalicular Plug

DEVICE CLASSIFICATION / PRODUCT CODE Unclassified
LZU

III. PREDICATE DEVICE

PREDICATE DEVICE: Oasis Form Fit
K040912
Partners in Biomaterials, Inc.

IV. DEVICE DESCRIPTION

The Visant Medical Canalicular Plug is designed to temporarily block tear drainage by the occlusion of the canaliculus of one or both eyelids in a given patient, thus maintaining lubricating tears on the surface of the eye. The Visant Plug consists of a transparent hydrogel, manufactured from cross-linked hyaluronic acid, that is designed for insertion into the canaliculus.

The Visant Medical Canalicular Plug is inserted into the lower canaliculus of the patient's eyelid by the healthcare practitioner, using a commercially available lacrimal cannula attached to the 0.6 mL gel-filled syringe which pushes the gel into the lower punctum until the recommended volume of gel (0.2 mL) is inserted.

V. INTENDED USE AND INDICATIONS FOR USE

The Visant Medical Canalicular Plug has the same intended use as the predicate. It is intended to temporarily block tear drainage by the occlusion of the canalicular system. The Visant Medical Canalicular Plug will have the following Indications for Use (IFU) statement:

The Visant Medical Canalicular Plug is intended to block tear drainage by occlusion of the canalicular system. It is indicated for use, for up to 6 months, in patients experiencing dry eye symptoms.

The IFU statement for the Visant Medical Canalicular Plug is not substantially different from that of the predicate device.

VI. TECHNOLOGICAL CHARACTERISTICS COMPARISON

A comparison of the key characteristics of the subject and predicate devices are presented in the following table.

VISANT MEDICAL, INC. CANALICULAR PLUG
510(K) SUBSTANTIAL EQUIVALENCE COMPARISON

	SUBJECT DEVICE	PREDICATE DEVICE
	Visant Medical Canalicular Plug	**Form Fit® Hydrogel Canalicular Plug K040912**
Manufacturer	**Visant Medical**	**Partners in Biomaterials, Inc. (Oasis Medical)**
Product Code(s)	LZU	LZU
Intended Use	To block tear drainage by the occlusion of the of the canalicular system.	To block tear drainage by the occlusion of the of the canalicular system.
IFU statement	The Visant Medical Canalicular Plug is intended to block tear drainage by occlusion of the canalicular system. It is indicated for use, for up to 6 months, in patients experiencing dry eye symptoms	The Hydrogel Canalicular Plug is intended for use in patients experiencing dry eye symptoms such as redness, burning, reflex tearing, itching, or foreign body sensations, which can be relieved by blocking of the punctum. The Hydrogel Canalicular Plug may be used in the treatment of dry eye syndrome and the dry eye component of various ocular surface diseases. When indicated, the Hydrogel Canalicular Plug may be used after surgery of the eye to prevent complications due to dry eye and to enhance the retention of ocular medications on the eye. Patients

	SUBJECT DEVICE	PREDICATE DEVICE
	Visant Medical Canalicular Plug	**Form Fit® Hydrogel Canalicular Plug K040912**
		experiencing dry eye related contact lens problems may also be aided by the Hydrogel Canalicular Plug.
Principle of Operation	Inserted into the canalicular system as a hydrated, cross-linked, particulated hydrogel plug. The gelatinous material fills the lumen in order to block tear drainage through the lacrimal drainage system.	Inserted into the canalicular system as a dry hydrogel plug and swells to form a gelatinous material when it contacts tear film. The gelatinous material fills the lumen in order to block tear drainage through the lacrimal drainage system.
Plug Material	Hydrogel (Cross-linked, particulated hyaluronic acid gel)	Hydrogel (semi-rigid rod of polyvinyl pyrrolidone based hydrogel)
Biocompatibility Established	Yes	Yes
Preloaded (Yes/No)	Yes (prefilled syringe)	Yes (preloaded on an inserter)
Removable (Yes/No)	Yes, particulated, gelatinous, non-degradable material can be removed via irrigation of the canalicular system	Yes, gelatinous, non-degradable material can be removed via irrigation of the canalicular system
Sizes	No need for individual sizing. Upon insertion, it fills the lumen.	No need for individual sizing. In its dry state, measures 0.3 mm in diameter by 2.5 mm long. In its hydrated state, it fills the lumen.
Sterilization	Steam	Gamma

The Visant Medical Canalicular Plug and the predicate device do not share identical technological characteristics, however, those differences do not raise different types of questions of safety and effectiveness.

The Visant Canalicular Plug and the predicate device share the same mechanism of action and are made from gelatinous material that fills the lumen in order to block tear drainage through the lacrimal drainage system. Both plugs are composed of biocompatible, sterilized, non-degradable hydrogel materials that do not require individualized sizing and that can be removed via irrigation of the canaliculus.

VII. PERFORMANCE DATA

A. NON-CLINICAL TESTING

Non-clinical investigations included biocompatibility and physicochemical testing, as well as in vivo studies to establish the safety of the device.

The following battery of tests were conducted on the Visant Medical Canalicular Plug:

- Cytotoxicity: ISO 10993-5: 2009, Non-cytotoxic
- Genotoxicity: ISO 10993-3: 2014: Ames Mutagenicity, Non-mutagenic Chromosomal Aberration, Non-mutagenic
- Systemic Toxicity: ISO 10993-11: 2017, No acute toxicity
- Material Mediated Pyrogenicity: ISO 10993-11:2017, USP <151>, Non-pyrogenic
- Guinea Pig Maximization Skin Sensitization: ISO 10993-10: 2010/(R)2014, Non-sensitizing
- Intracutaneous Reactivity: ISO 10993-10: 2010/(R)2014, Saline extract caused skin irritation, similar to that observed with other commercially available crosslinked HA products, below a level of concern
- Ocular Irritation: ISO 10993-10: 2010/(R)2014, Non-irritating
- Pre-sterilization Bioburden Determination, ISO 11737-1:2018
- Endotoxin (Limulus Amoebocyte Lysate, LAL): USP <85>, AAMI ST72, meets the <20 Endotoxin Units (EU)/device specification limit

Testing was also conducted on the primary packaging (the syringe) of the device, with the following results:

- Cytotoxicity: ISO 10993-5: 2009, Non-cytotoxic
- Systemic Toxicity: ISO 10993-11: 2017, No acute toxicity
- Guinea Pig Maximization Skin Sensitization: ISO 10993-10: 2010/(R)2014, Non-sensitizing
- Intracutaneous Reactivity: ISO 10993-10: 2010/(R)2014, No reactivity
- Material-Mediated Pyrogenicity: ISO 10993-11: 2017, Non-pyrogenic
- Chemical Characterization and Toxicological Risk Assessment: ISO 10993-18: 2005, via FTIR, GC-MS, ICP-MS, ICP-MS (Mercury), UPLC-MS, GC-MS (Headspace), IC: Extractable substances identified; No substances at the threshold of toxicity concern
- Container Closure Integrity: ISO 11040-8:2016, No dye ingress
- Test of Sterility: ISO 11737-2:2009/(R)2014, Sterile (no growth observed)

In addition to the above, a GLP implantation study of the device in the nasolacrimal ducts of rabbits was conducted. This study showed no subchronic toxicity, chronic toxicity, or tissue irritation in any of the animals sacrificed either at 14, 90, or 180 days. However, these results were difficult to interpret for a subgroup of animal subjects since the residence

time of the plug in this animal model could not be determined with certainty for all subjects.

Steam sterilization validation was performed in accordance with ISO 17665-1:2006, and the sterilization process was demonstrated to achieve a Sterility Assurance Level (SAL) of 10^{-6}. Additional testing was successfully completed for sterilization, packaging, and product performance following real-time shelf-life storage confirm the long-term stability of the device.

B. CLINICAL PERFORMANCE EVALUATION

Trial Summary

A prospective, multicenter, randomized, double masked, controlled clinical trial was performed to evaluate the clinical performance of the Visant Medical Canalicular Plug compared to the predicate device over 6 months of participant follow-up. Eligible participants age 22 or older with ocular signs and symptoms consistent with dry eye syndrome and with bilateral lacrimal drainage system patency as demonstrated by punctal irrigation were randomly assigned in a 2:1 ratio (Visant:Oasis Form Fit) to undergo bilateral implantation in the inferior canaliculus with the Visant plug or the Oasis Form Fit plug. Participants had a baseline examination within 30 days prior to the initial treatment with either the Visant plug or control. Scheduled follow-up visits occurred at Week 1, Month 1, Month 3, and Month 6. All participants underwent plug removal via lacrimal irrigation at the 6 month visit (if it not already removed at an earlier timepoint).

Participant Disposition

157 participants were enrolled and randomized. The safety population included 157 participants (103 in the Visant plug group, 54 in the control group). The intent-to-treat (ITT) population was comprised of 156 participants (103 in the Visant plug group, 54 in the control group); one participant in the Visant group did not have the device successfully applied. 151 participants comprised the per-protocol (PP) population (99 in the Visant plug group, 52 in the control group). Exclusions from the PP cohort were comprised of three participants (3%) in the Visant plug group and two (4%) from the control group had major protocol deviations. 151 participants (96.2%) completed the trial, and six (3.8%; four in the Visant plug group, two in the control group) were discontinued.

Demography and Baseline Characteristics

The majority of participants (118/156, 75.6%) were women (74/102 [72.5%] in Visant plug group; 44/54 [81.5%] in the control group). The mean age was 62.9±11.66 years (range 26 to 84; mean age in Visant group 61.9±12.42 [range 26 to 84], mean age in control group 64.9±9.86 [range 47 to 82]). The majority of participants (125/156, 80.1%) identified as white (79/102 [77.5%] Visant group; 46/54 [85.2%] control group). 15 of 156 (9.6%) identified as Black or African-American (12/102 [11.8%] in the Visant group; 3/54 [5.6%] in the control group). 13 of 156 participants identified as Asian (9/102 [8.8%] in the Visant group; 4/54 [7.4%] in the control group). Two Visant-group participants identified as other race and one control-group participant identified has being of multiple races. The majority

(147/156, 94.2%) did not identify as Hispanic or Latino (97/102 [95.1%] Visant group; 50/54 [92.6%]).

152 of 157 (96.8%) were previously documented with having dry eye syndrome (99/103 [96.1%] Visant group, 53/54 [98.1%] control group). 26 of 157 participants (16.6%) had previously undergone laser keratomileusis (20/103 [19.4%] Visant group; 6/54 [11.1%] control group) and 25 of 157 (15.9%) had previously undergone cataract extraction (18/103 [17.5%] Visant group; 7/54 [13.0%]). 31 of 157 (19.7%) had documented history of meibomian gland dysfunction (20/103 [19.4%] Visant group, 11/54 [20.4%] control group). 13 of 157 (8.3%) had documented history of blepharitis (11/103 [10.7%] Visant group, 2/54 [3.7%] control group). Baseline best-corrected distance visual acuity (BCDVA) was -0.009±0.12 logMAR (range, -0.30 to 0.36 logMAR) in the right eye and 0.002±0.12 logMAR (range, -0.30 to 0.42 logMAR) in the left eye.

The baseline value for the anesthetized Schirmer's test was 5.5±2.71 mm (right eye; 5.5±2.75 mm [range, zero to 10 mm] Visant group, 5.6±2.67 mm [range, 1 to 10 mm] control group) and 5.3±3.01 mm (left eye; 5.2±3.05 mm [range, zero to 10 mm] Visant group, 5.4±2.97 mm [range, 1 to 10 mm] control group), range, zero to 10 mm for both eyes. Baseline mean tear meniscus heights were 0.915±1.57 mm (range, 0.05 to 8.67 mm) in the right eye (0.941±1.61 mm [range, 0.05 to 8.67 mm] Visant group, 0.866±1.52 [range, 0.08 to 7.67 mm] control group) and 0.866±1.4899 (range, 0.06 to 10.67 mm) in the left eye (0.914±1.62 mm [range, 0.10 to 10.67 mm] Visant group, 0.776±1.22 mm [range, 0.06 to 6.33 mm] control group). Baseline mean corneal fluorescein staining scores were 5.9±3.35 (range, 1 to 15) in the right eye (5.8±3.43 [range, 1 to 15] Visant group; 6.0±3.23 [range, 1 to 15] control group) and 5.9±3.17 in the left eye (5.9±3.25 [range, 1 to 15] Visant group; 6.1±3.03 [range, 1 to 15] control group). Baseline tear break-up time (TBUT) was 3.02±1.49 seconds (range, 0.17 to 11.25 seconds) in the right eye (2.98±1.51 seconds [range, 1.06 to 11.25 seconds] Visant group; 3.10±1.47 seconds [range, 0.17 to 6.74 seconds] control group)

Baseline mean total score on the Ocular Surface Disease Index© (OSDI) questionnaire was 48.0±16.38 (range, 25 to 93); 48.8±17.49 (range, 25 to 93) in the Visant group, 46.4±14.07 (range, 25 to 79) in the control group. The baseline mean OSDI score for the ocular symptoms subscale (Items 1 through 5) was 42.4±18.09 (range, 10 to 95); 44.0±19.43 (range, 10 to 95) in the Visant group and 39.4±14.97 (range, 10 to 70) in the control group. The baseline mean OSDI score for the vision-related functional subscale (Items 6 through 9) was 47.0±23.25 (range, zero to 100); 48.2±23.31 (range, zero to 100) in the Visant group, 44.7±23.20 (range, zero to 88) in the control group. The baseline mean OSDI score for the environmental triggers subscale (Items 10 through 12) was 59.0±26.34 (range, zero to 100); 57.9±27.05 (range, zero to 100) in the Visant group, 61.0±25.09 (range, zero to 100) in the control group.

Effectiveness Results Summary

At Month 3, for the right eye, the mean change in anesthetized Schirmer's test score was 3.40±7.54 mm (range, -7.0 to 30.0 mm) in the Visant group (95% confidence interval [CI] 1.88-4.92 mm) and 1.78±5.44 mm (range, -7.0 to 21 mm) in the control group (95% CI

0.23-3.33 mm). For the left eye, the mean change in anesthetized Schirmer's test score was 3.38±7.005 mm (range, -8.0 to 31.0 mm) in the Visant group (95% CI 1.97-4.79 mm) and 2.24±5.76 mm (range, -8.0 to 25.0 mm) in the control group (95% CI 0.60-3.88 mm). The LS mean between-group difference was 1.19±1.16 mm (95% CI -1.10 to 3.48 mm). At Month 3, 83 of 99 (83.8%) Visant group participants and 44 of 52 (84.6%) control group participants had an improvement in OSDI questionnaire score of at least 4.5 for those with moderate baseline symptoms or at least 7.3 for those with severe baseline symptoms. The mean proportional difference was -0.028 (95% CI -0.139 to 0.083).

Safety Results Summary

93 of 157 participants in the safety population (59.2%) reported a total of 242 adverse events (AEs). There were 238 TEAEs (treatment-emergent adverse events) reported. 59 participants (57.3%) in the Visant Plug group reported 152 TEAEs, 34 (63.0%) in the control group reported 86 TEAEs.

Most of the participants experienced TEAEs that were classified as mild (62 total [39.5%], 38 [36.9%] in the Visant Plug group and 24 [44.4%] in the control group). TEAEs in 27 participants [17.2%] (18 [17.5%] in the Visant Plug group and 9 [16.7%] in the control group) were reported as moderate severity. TEAEs in four participants [2.5%] (3 [2.9%] in the Visant Plug group, one [1.9%] in the control group) were classified as severe. One Visant-group participant reported experiencing ocular severe TEAEs (excessive tearing) classified as related to the study device; this event was resolved without sequelae.

Corneal staining was reported in 60 (38.2%) participants (36.9% in the Visant Plug group, 40.7% in the Oasis Plug group). Ocular pain was reported in 10 (6.4%) participants (9.7% in the Visant Plug group and zero in the control group). One case of presumed dacryocystitis was reported in the Visant group. The event resolved without need for secondary surgical intervention. No dacryocystitis events were reported in the control group. Conjunctivitis events were reported in five Visant-group participants (4.9%) and one control-group participant (1.9%). Allergic blepharoconjunctivitis was reported in one Visant-group participant. Epiphora was reported in 7.8% (8/103) of the Visant group and 5.6% (3/54) of the control group.

Two participants (one in each group) experienced AEs leading to premature treatment discontinuation. No participants experienced TEAEs leading to withdrawal. Three Visant-group participants (3/102, or 2.9%) and one control-group participant (1/54 or 1.9%) underwent an unplanned removal attempt due to an AE. There were two Visant-group participants who underwent unplanned device removal not due to an AE (voluntary withdrawals).

Questionnaires were administered to investigators to assess the ease of device insertion and the ease of device removal. On the insertion questionnaire, the mean response score to the question "How easy was it to insert the plugs?" (on a scale from 1 to 5, higher scores indicating greater difficulty) was 1.8±1.19 (range, 1 to 5) in the Visant group and 1.4± 0.88 (range, 1 to 5) in the control group for the right eye; response scores were similar for the left eye. Difficulty inserting the device was reported for 26 Visant-group participants

(25.5%) and two control-group participants (3.7%). Pain during the procedure as reported by the participant to the investigator (on a scale from 1 to 5, higher scores indicating more severe pain) were 1.4±0.77 (range, 1 to 4) in the Visant group (right eyes) and 1.3±0.91 (range, 1 to 5) in the control group (right eyes; results similar for left eyes in both groups).

The removal questionnaire consisted of four questions (regarding reflux from puncta during irrigation; how easy it was to irrigate the plug; any difficulties encountered during irrigation; patency of the lacrimal drainage system). Reflux from the right punctum during irrigation was observed in 31/101 (30.7%) and 15/51 (29.4%) of the Visant- and control-group participants, respectively. Ease of irrigation (on a scale from 1 to 5, higher scores indicating greater difficulty) score was 1.9±1.10 (range, 1 to 5) in the Visant group (right eyes) and 1.6±0.92 (range, 1 to 4) in the control group (right eyes; left eye results similar). Difficulties encountered during right punctum irrigation were reported in 8/101 (7.9%) Visant participants and 2/51 (3.9%) of control participants (similar results were reported for the left punctum). Patency of the lacrimal drainage system was deemed re-established by the investigator in 100/101 Visant eyes (both right and left; 99.0%) and 51/51 control eyes (both right and left; 100%). Resistance encountered during infusion of the irrigation solution was reported in eight Visant and two control participants.

VIII. CONCLUSIONS

The Visant Medical Canalicular Plug has the same intended use as the legally marketed predicate device identified in this 510(k) notification. The Indications for Use statement differs from that of the predicate device, but the differences do not alter the intended use of the device. The technological characteristics of the Visant Medical Canalicular Plug differ from those of the predicate device, but these differences do not raise new or different types of questions of safety or effectiveness. Results of the non-clinical and clinical performance testing support a determination of substantial equivalence between the Visant Medical Canalicular Plug and the predicate device.