DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 15, 2015

Pierrel Pharma S.r.l.
c/o Mr. Maurizio Pantaleoni
Isemed Srl
Via A. Bonetti 3/A
Imola, 40026 BO
ITALY

Re: K151630
Trade/Device Name: G.o.c.c.l.e.s.
Regulation Number: 21 CFR 872.6350
Regulation Name: Ultraviolet Detector
Regulatory Class: II
Product Code: NXV
Dated: June 10, 2015
Received: June 17, 2015

Dear Mr. Pantaleoni:

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" (21 CFR 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,

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151630

Device Name
G.o.c.c.l.e.s.

Indications for Use *(Describe)*

G.o.c.c.l.e.s. is intended to be used by a qualified health–care providers to enhance the identification and visualization of the oral mucosal abnormalities that may not be apparent or visible to the naked eye, such as oral cancer and premalignant dysplasia. G.o.c.c.l.e.s. eyewear is reusable filtered eyewear that is worn by a health care professional to enhance the visual effects of blue light during oral exam

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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510(k) Summary

G.o.c.c.l.e.s.

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

2.1. General Information

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Summary Preparation Date: June 10, 2015

2.2. Names

Device Name: G.o.c.c.l.e.s.
Classification Name: Ultraviolet Detector
Product Code: NXV
Regulation number: 872.6350
Classification: II

2.3. Predicate Device

G.o.c.c.l.e.s. is substantially equivalent to the following devices:

Applicant	*Device name*	*510(k) Number*
TRIMIRA LCC	TRIMIRA Identafi 3000, Remicalm LCC	K090135
LED Dental Incorporated	VELscopeVx, LED Dental Incorporated	K102083

2.4. Device Description

The *G.o.c.c.l.e.s* device consist of one eyewear with specific filtering features that shall be used with the *G.o.c.c.l.e.s. light* proprietary light source (emission range 440-490nm), in order to allow the examination of autofluorescence of the oral cavity and consequently detect oral abnormalities such as dysplastic or anaplastic lesions (carcinomas of the oral mucosa).

The device looks like a pair of glasses, characterized by reduced dimensions, good wearability, easy portability and proper filtering performances in order to allow to filter the fluorescence emission, resulting from the fluorophore of interest (Flavin Adenine Dinucleotide (FAD)), which in its oxidized form responds to a light of 450nm (blue-violet) emitting a fluorescence wavelength of around 515nm (green).

2.5. Indications for Use

G.o.c.c.l.e.s. is intended to be used by a qualified health–care providers to enhance the identification and visualization of the oral mucosal abnormalities that may not be apparent or visible to the naked eye, such as oral cancer and premalignant dysplasia. G.o.c.c.l.e.s. eyewear is reusable filtered eyewear that is worn by a health care professional to enhance the visual effects of blue light during oral exam.

Such intended use is equivalent to the intended use of the predicate devices K090135.

Also, both the subject and the predicate (K090135 and K102083) are for prescription use, to be used by physicians.

2.6. Comparison of technological characteristics with the predicate devices.

At high level the subject and the predicate devices are based on the following same technological elements:

- Device Composition: Similar to the predicate devices K090135 and K102083, theG.o.c.c.l.e.s consists of a filtering system to be used with a proprietary light source in order to allow illumination of the oral cavity and the transmission of the fluorescence of the fluorophore of interest. Similarly to the predicate K090135 the filtering system of the G.o.c.c.l.e.s. is represented by a pair of eyewear and the light source is a proprietary light not integrated into the vision system.
- Performance features: Simmilar to the predicate devices K090135 and K102083, the G.o.o.c.l.e.s. performance is based on the capacity of the filtering system to detect and transmit the fluorescence emitted by the fluorophore of interest (FAD).
- Light source- emission range: the subject as well as the predicate devices define proper emission range which has to be compatible with the excitation of the fluorophore of interest.

Specifically the fluorophore FAD is characterized by an excitation peak at 450 nm and a maximum emission around 515-530 nm. Consistently, both the subject and the predicate devices are to be used with a light source with an emission spectrum including 450 nm.

- Transmittance range:G.o.c.c.l.e.s. is characterized by a filtering system with a transmittance range 470-610 nm which include the emission wavelengths of the fluorophore FAD (around 515 nm). Equivalently, the predicate devices are characterized by a transmittance range including 515nm.

The following technological differences exist between the subject and the predicate devices:

- Light source emission range: Equivalently to the predicate device K090135, the G.o.c.c.l.e.s. is provided with a proprietary light source separated from the vision system in order to illuminate the cells of the oral cavity so that they can be excited and emit fluorescence. The specific emission range of the G.o.c.c.l.e.s. light is 440-490 nm while the emission range of the predicate devicesK090135 and K102083arearound 380-460 nm and 400-460 nm respectively. Despite the specific emission range both the G.o.c.c.l.e.s' and the predicate devices' emission range includes the excitation peak of the fluorophore of interest (FAD) which is around 450 nm. Also the performance of the subject device has been tested through a specific performance (clinical test) demonstrating the ability of the G.o.c.c.l.e.s. to transmit the fluorescence of FAD after illumination of cells by the G.o.c.c.l.e.s. light (see below), according to its intended use.
- Transmittance range: the specific transmittance range of the G.o.c.c.l.e.s. is 470-610 nm while the transmittance range of the predicate is different (400-460nm). However the transmittance range of the subject as well as the predicate devices include the emission peak of the fluorophore of interest (FAD's emission peak around 515 nm). Also, the intended use of the G.o.c.c.l.e.s. filtering system has been proved through specific performance tests underlining the capacity of the G.o.c.c.l.e.s. to properly filter and transmit the FAD's fluorescence after the excitation by the G.o.c.c.l.e.s. light emitting at 450 nm (corresponding to the excitation peak of FAD). See below for performance tests.

2.7. Performance Data

The following performance tests have been conducted with the purpose of: 1) verifying the transmittance characteristics of the G.o.c.c.l.e.s. device in order to verify their compatibility with regard to the excitation and emission spectrum of the FAD which is the fluorophore of interest; 2) validating the performance of the G.o.c.c.l.e.s. device when used in combination with either the G.o.c.c.l.e.s. light or a non proprietary light source emitting in a range compatible with the FAD's excitation.

- Verification of the Transmittance range of the G.o.c.c.l.e.s.

Evaluation: the transmittance % for the G.o.c.c.l.e.s eyewear was measured by scanning the light spectrum from 1400 to 200nm and measuring the quantity of UV transmitted

by the G.o.c.c.l.e.s eyewear filter. The transmittance % was calculated as the ratio between the intensity of the incident light (e = 100) and that of light passing the filter expressing it as%.
Results: The result of the measurements of this performance study shows that the transmittance % for the G.o.c.c.l.e.s eyewear filter has its maximum at 518nm with a % of transmittance of 66.842 with a bandwith between 470 and 610 nm and with a transmittance % that remains over the 90% of its max value (60.000) from 500nm to 541nm covering the typical bandwidth that allows to enable the visualization of the response signal of FAD which is maximum at the wavelengthsaround515-530 nm.
Discussion and Conclusion: the obtained results demonstrate that the G.o.c.c.l.e.s.'s transmittance range covers exactly the excitation curve of the fluorophore of interest (FAD) allowing the detection and transmission of the related fluorescence. Therefore such evidence corroborates the intended use of the subject device and validates its performance equivalently to the predicate devices.

- <u>Validation of the non-proprietary light source</u>

  1- *Aim*: A specific test was conducted to demonstrate the performance of the G.o.c.c.l.e.s. device used with a common non proprietary light source.

  The study was carried out by A. Moro et al. that led to the publication "Autofluorescence and Early Detection of Mucosal Lesions in Patients at Risk for Oral Cancer

  Methods: In this study, 32 patients with risk for oral cancer underwent autofluorescence test. Of these patients,12 (group A) experienced potentially malignant diseases. The other 20 patients (group B) were previously operated for oral cancer.

  The autofluorescence was detected using a light source consisting of an LED emitting in the band of 400-500nm with a peak at 450nm and a pass-band filtering system identical to the filtering system used for the manufacturing of the G.o.c.c.l.e.s device.

  The lesions suspected to be tumors by the autofluorescence inspection were surgically excised and histologically analyzed to confirm the diagnosis

  Results: overall the autofluorescence detected 15 suspected cancer of which 14 were confirmed by the histological analyses.

  Discussion and Conclusion: the clinical test demonstrates that the subject device detects the fluorescence of the cells of the oral cavity when illuminating by a light source emitting in a range including FAD's excitation peak (450 nm). Such evidence supports the intended use of the G.o.c.c.l.e.s. and also, they corroborate the mechanism of action and final performance of the subject device is equivalent to those of the predicate devices: in all cases the fundamental aspect to be satisfied is guaranteeing the excitation of FAD (by a light source emitting at 450 nm) and the transmission of FAD's fluorescence (by a filtering system transmitting around 515 nm, according to FAD's emission peak).

2- *Aim*: A specific performance clinical test has been conducted in order to prove the ability of the subject device to detect oral cavity cancer when used with its proprietary compatible light source (G.o.c.c.l.e.s. light) as well as with other two light sources (curing lights), accordingly to the consideration that the light source to be used with G.o.c.c.l.e.s. needs to have an emission spectrum including the excitation peak of FAD (450 nm).
Methods: Multicenter studyrecruiting patients affected by diseases of the oral cavity that are suspected of being cancer or may lead to cancer, as well as patients in follow-up process after surgical operation for oral carcinoma.
All patients were examined by Goccles in combination with three light sources that are legally marketed and FDA-cleared:

→ Optilux 501 (K020091)- emission range: 400 nm-505nm

→ G.o.o.c.c.l.e.s. light (which correspond to the light cleared under K080025) – emission range 440 nm- 490 nm

→ Eliparfreelight (K011154)-emission range 440-490 nm

All the lesions as detected by G.o.c.c.l.e.s. (spots of fluorescence loss) with either the lights were surgically removed and histologically analyzed to confirm the diagnosis of dysplasia/cancer as detected in the previous step and to evaluate the size and the infiltration rate of each lesion
Results: the visual inspection by G.o.c.c.l.e.s. identified loss of fluorescence in a total of 35 cases (false positive+true positive) of which 29 were confirmed by the histological analyses to be real dysplasia or carcinoma in situ or invasive cancer (true positive). There were no relevant differences in the G.o.c.c.l.e.s. performance depending on the specific light that was used.
Discussion and Conclusion: the results support the use of G.o.c.c.l.e.s. with the G.o.c.c.l.e.s. light. Such evidence underline that the the capacity of emitting at 450 nm represents the fundamental criteria that the light to be used with G.o.c.c.l.e.s must satisfy and thus they support the performance of the G.o.c.c.l.e.s. light, according to its intended use. In conclusion the obtained results demonstrate the performance of the G.o.c.c.l.e.s validating its use with the G.o.c.c.l.e.s light since it emits in a range including the maximum excitation peak of the FAD (450 nm), equivalently to the predicate devices.

** Please note that even though both studies included other proprietary light sources, only the G.o.c.c.l.e.s. light is intended to be used with the G.o.c.c.l.e.s. eyewear. This study serves to prove the more important concept that the eyewear measurably transmits FAD fluorescence.

2.8 Conclusions

The performance data described above demonstrate that the G.o.c.c.l.e.s. device performs as intended in the specific use conditions. The considerations discussed above underline the equivalence of the subject device to the predicate devices K090135 and K102083 concerning the intended use, the device composition and mechanism of action. Indeed the subject as well

as the predicate devices are based on similar performance features and are characterized by equivalent filtering system with a transmittance range including the emission peak of the fluorophore of interest (around 515nm). Further, the performance tests demonstrate the performance of the G.o.c.c.l.e.s. device when used in combination with the G.o.c.c.l.e.s. light.
Thus, on the basis of evidence discussed above, the G.o.c.c.l.e.s. device may be found substantially equivalent to the predicate devices K090135 and K102083.