DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 18, 2014

Oculus Innovative Sciences, Inc.
Mr. Brian W. Martin
Director of Regulatory Affairs and Quality Control
1129 North McDowell Blvd.
Petaluma, CA 94954

Re: K141352
Trade/Device Name: Endocyn Root Canal Irrigation Solution
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Unclassified
Product Codes: KJJ
Dated: June 11, 2014
Received: June 12, 2014

Dear Mr. Martin:

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

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)*
K141352

Device Name
Endocyn Root Canal Irrigation Solution

Indications for Use *(Describe)*
Endocyn Root Canal Irrigation Solution is intended to irrigate, cleanse, and debride root canal systems including the removal of foreign material and debris during root canal therapy. It is also intended to provide for lubrication and irrigation during root canal instrumentation.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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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."

510(k) SUMMARY

The following is a summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

510(k) Owner
Oculus Innovative Sciences, Inc.
1129 North McDowell Blvd.
Petaluma, CA 94954
Phone: (707) 283-0550
Fax: (707) 283-0551

Official Contact
Brian W. Martin
Director of Regulatory Affairs and Quality Control

Device Information

Trade or Proprietary Name:	Endocyn Root Canal Irrigation Solution
Common Name:	Endodontic Cleanser
Classification Name:	Cleanser, Root Canal
Regulation:	21 CFR Unclassified, Pre-amendment status
Product Code(s)	KJJ
Device Panel	Dental
Legally marketed device(s) to which equivalence is claimed:	Aquatine EC Endodontic Cleanser manufactured by PuriCore (K061689) and Sodium Hypochlorite 3% and 6% and 6% Sodium Hypochlorite with wetting agents marketed as Chlor-XTRA manufactured by Inter-Med, Inc./Vista-Dental, Inc. (K082470)
Reason for 510(k) submission	New Device
Device Description	The Endocyn Root Canal Irrigation Solution is a colorless, slightly chlorinated odor, clear aqueous solution intended to irrigate, cleanse, and debride root canal systems. The solution will be supplied in polyethylene terephthalate (PET) round-bottles with polypropylene (PP) screw-top closure.
Intended Use	Endocyn Root Canal Irrigation Solution is intended to irrigate, cleanse, and debride root canal systems including the removal of foreign material and debris during root canal therapy. It is

	also intended to provide for lubrication and irrigation during root canal instrumentation.
Performance Testing	The following tests were reviewed to support the performance of the Endocyn Root Canal Irrigation Solution: package integrity, visual inspection, pH, osmolality, free available chlorine, and bioburden. The Endocyn Root Canal Irrigation Solution meets specification and performance characteristics and is substantially equivalent to the predicate devices.
Biocompatibility Testing	Biocompatibility Testing of the Oculus Endocyn Root Canal Irrigation Solution confirmed that the device meets the applicable requirements of the Blue Book Memorandum G95-1 entitled Use of International Standards ISO-10993 Biological Evaluation of Medical Devices and is biocompatible.
Safety and Effectiveness	The Endocyn Root Canal Irrigation Solution does not raise any new safety and efficacy concerns when compared to a similar device already legally marketed.

Substantial Equivalence (SE) Rationale

	Endocyn Root Canal Irrigation Solution	**Aquatine EC Endodontic Cleanser**	**Sodium Hypochlorite 3% and 6%**
Regulatory Status	Present application	Predicate	Predicate
510(k) Number	K141352	K061689	K082470
Product Code	KJJ	KJJ	KJJ
Indications for Use	Endocyn Root Canal Irrigation Solution is intended to irrigate, cleanse, and debride root canal systems including the removal of foreign material and debris during root canal therapy. It is also intended to provide for lubrication and irrigation during root canal instrumentation.	Intended to irrigate, cleanse, and debride root canal systems.	Sodium Hypochlorite 3% and 6% and Sodium Hypochlorite 6% with wetting agents to lower surface tension marketed as Chlor-XTRA are solutions used for debridement and the instrumentation of root canal. Sodium Hypochlorite-3% and 6% and Chlor-XTRA 6% are Sodium Hypochlorite in water.
Sterility	Non-sterile	Non-sterile	Non-sterile
Delivery System	Aqueous solution	Aqueous solution	Aqueous solution

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The Endocyn Root Canal Irrigation Solution is substantially equivalent in intended use, technological characteristics, safety and effectiveness to the Aquatine EC Endodontic Cleanser manufactured by PuriCore (K061689) and Sodium Hypochlorite 3% and 6% manufactured by Inter-Med, Inc./Vista-Dental, Inc. (K082470). Therefore, the Oculus Endocyn Root Canal Irrigation Solution is substantially equivalent to the predicate devices.

Submitted by: Brian W. Martin
Director of Regulatory Affairs and Quality Control

06/11/2014

Date Submitted: June 11, 2014