6. 510(k) Summary

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

APPLICANT:	Arges Imaging, Inc.
DATE PREPARED:	September 9, 2011
CONTACT PERSON:	Rebecca K Pine 129 N Hill Ave Pasadena, CA 91106 Phone: 760.809.5178 Fax: 760.290.3216
TRADE NAME:	Arges Imaging Contrast Spray
CLASSIFICATION NAME:	Impression Material
DEVICE CLASSIFICATION:	Class II
REGULATION NUMBER	872.3660
PRODUCT CODE	ELW
PREDICATE DEVICES:	CEREC Opti Spray (K080882)

Substantially Equivalent To:
The Arges Imaging Contrast Spray is substantially equivalent in intended use, principal of operation and technological characteristics to the CEREC Opti Spray.

Description of the Device Subject to Premarket Notification:

The Arges Imaging Contrast Spray is a pigment suspension in ethanol with a fluorinated hydrocarbon propellant. The Arges Imaging Contrast Spray is a coating medium which is applied to teeth and surrounding areas. A 3D impression of the coated dentition is taken using a commercially available CAD/CAM system. Upon completion of the impression scan, the patient's mouth if rinsed and suctioned to remove the Arges Imaging Contrast Spray.

Indication for Use:

Arges Imaging Contrast is indicated as a coating medium for optical impressions. It aids in intraoral topographical recordings of prepared and unprepared teeth and their surroundings.

Technological Characteristics:

The Arges Imaging Contrast Spray has the same technological characteristics and is similar in overall design, materials and configuration compared to the predicate device. It is substantially equivalent to the predicate in terms of:

- Indications for Use
- Basic design/configuration
- Where used
- Target population
- Delivery method

Testing and Performance Data:

The biocompatibility of the Arges Imaging Contrast Spray materials was evaluated following the principles of ISO 10993-1.

Bench testing, including dimensional verification and functional testing was completed to support substantial equivalence of the Arges Imaging Contrast Spray. In all cases the Arges Imaging Contrast Spray performed as intended with acceptable results.

Conclusion: The Arges Imaging Contrast Spray was found to be biocompatible for its intended use and substantially equivalent in performance characteristics when compared to the predicate devices.

Basis for Determination of Substantial Equivalence:

Upon reviewing and comparing intended use, design, materials, principle of operation and overall technological characteristics, the Arges Imaging Contrast Spray is determined by Arges Imaging, Inc. to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Arges Imaging, Inc.
C/O Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

NOV 14 2011

Re: K113263
Trade/Device Name: Arges Imaging Contrast Spray
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: November 3, 2011
Received: November 4, 2011

Dear Mr. Job:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K113263

Device Name: **Arges Imaging Contrast Spray**

Indications for Use:

Arges Imaging Contrast is indicated as a coating medium for optical impressions. It aids in intraoral topographical recordings of prepared and unprepared teeth and their surroundings.

OR

Prescription Use __X__
(Per 21 CFR 801 Subpart D)

Over-The-Counter Use_____
(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113263