DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 29, 2015

Dupaco, Inc.
c/o Mr. Greg Holland
Regulatory Consultant
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606

Re: K150518
Trade/Device Name: Airway with Bite Block and Tongue Depressor
Regulation Number: 21 CFR 882.5070
Regulation Name: Bite Block
Regulatory Class: II
Product Code: JXL, CAE
Dated: March 30, 2015
Received: March 31, 2015

Dear Mr. Holland:

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" (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 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division 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)*
K150518

Device Name
Airway with Bite Block and Tongue Depressor

Indications for Use *(Describe)*
The Airway with Bite Block and Tongue Depressor is a combined oral airway and bite block that will allow an anesthesia provider to establish a patent airway in an anesthetized patient while simultaneously preventing occlusion of the teeth. It is intended for use during Electroconvulsive Therapy (ECT) procedures or whenever a bite block is required to prevent occlusion of an endotracheal tube.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) Summary or 510(k) Statement

510(k) SUMMARY

510(k) Owner	Dupaco Inc. 4144 Avenida de la Plata Oceanside, CA 92056 TEL: 800.546.4550 FAX: 760.758.1465
Contact person	Greg Holland Regulatory Consultant to Dupaco Inc. Regulatory Specialists, Inc. 3722 Ave. Sausalito Irvine, CA 92606 TEL: 949.262-0411 FAX: 949.552.2821 EMAIL: greg@regulatoryspecialists.com
Date summary was prepared	June 29, 2015
Name of device	Airway with Bite Block and Tongue Depressor
Common Name	Oral Airway and Bite Block
Classification Name	Bite Block
Regulation	882.5070
Product Code	JXL, CAE
Predicates	Epiguard (K050188) Veni-A-Oral Protector (K992269)

Description

The Airway with Bite Block and Tongue Depressor is a combined oral airway and bite block that will allow an anesthesia provider to establish a patent airway in an anesthetized patient while simultaneously preventing occlusion of the teeth. It is intended for use during ECT procedures and whenever a bite block is required to prevent occlusion of an endotracheal tube.

The Airway with Bite Block and Tongue Depressor is available in two sizes, Medium – 80 mm and Large – 90 mm.

Intended Use

The Airway with Bite Block and Tongue Depressor is intended for use as an oral airway and bite block.

Indications for Use

The Airway with Bite Block and Tongue Depressor is a combined oral airway and bite block that will allow an anesthesia provider to establish a patent airway in an anesthetized patient while simultaneously preventing occlusion of the teeth. It is intended for use during Electroconvulsive therapy (ECT) procedures or whenever a bite block is required to prevent occlusion of an endotracheal tube.

Technological Characteristics

The predicate and the Airway with Bite Block and Tongue Depressor were compared in the following areas and found to have similar technological characteristics and to be equivalent:

The following non-clinical performance tests were conducted:

Product compression testing

Biocompatibility to ISO 10993

Cytotoxicity

Irritation or Intracutaneous Reactivity

Sensitization

Oral Toxicity

	Airway with Bite Block and Tongue Depressor	**Epiguard (K050188)**	**Ventil-A (K992269)**
Indications for use	The Airway with Bite Block and Tongue Depressor is a combined oral airway and bite block that will allow an anesthesia provider to establish a patent airway in an anesthetized patient while simultaneously preventing occlusion of the teeth. It is intended for use during Electroconvulsive therapy (ECT) procedures or whenever a bite block is required to prevent occlusion of an endotracheal tube.	The EpiGuard is intended for the prevention of oral soft tissue damage during epileptic tonic-clonic seizures proceeded by an aura	The Somatics Ventil-A oral protector is a single-use oral protector for use during seizures induced by electroconvulsive therapy, spontaneous seizures, and circumstance requiring protection of the teeth, lips, tongue, and buccal mucosa (e.g., during cardioversion)
Product Code	JXL	JXL	JXL
Technical Characteristics	Combination device with airway, bite block and tongue depressor	Combination device with airway and bite block	Combination device with airway and bite block
Biocompatibility	Meets ISO 10993 requirements	Not known	Not known
Materials	Pellethane	Silicone	Not known
Sterility	Non Sterile	Non Sterile	Not known

Conclusions from non-clinical performance data

After performing non-clinical performance studies, the data shows that the Airway with Bite Block and Tongue Depressor is substantially equivalent to the predicates as an oral airway and bite block.