

NOV 23 2004

2. Modified 510(k) Summary

To Incorporate Bite Block Classification and Product Code

7.0 510(k) Summary of Safety and Effectiveness Information (*This document is not confidential*)

PRODUCT NAME

Proprietary: Smart BiteBloc™

Common: Bite Lock Endoscopy/Capnography Accessory

ESTABLISHMENT REGISTRATION NUMBER

Establishment Registration Number: 3003941644

ESTABLISHMENT ADDRESS:

Oridion Capnography Inc.

21 Highland Circle

Needham, MA 02494-3038

CONTACT PERSON:

Sanford Brown, Regulatory Affairs Director

Oridion Medical 1987 Ltd.

Har Hotzvim Science Based Industrial Park

POB 45025

91450 Jerusalem, Israel

Telephone: +972-2-589-9115

FAX: +972-2-586-6680

DEVICE LISTING FDA FORM 2892:

B051971

DEVICE DESCRIPTION

Bite blocks indicated for use as an endoscopy accessory are usually classified, according to 21CFR876.1500, as exempt from pre market notification. The submitted endoscopy accessory, Smart BiteBloc™, has been modified to allow the convenient use of an oral nasal cannula (K011536) for sampling of EtCO₂ and administration of O₂ during endoscopic procedures. Oridion considers this device to be a capnography accessory.

SUBSTANTIAL EQUIVALENCE INFORMATION

Predicate Devices

United States Endoscopy K954352

United States Endoscopy K924304

Endoscopix Bite Block K896691

GI Supply Bite Block K915816

GI Supply Oxy-Block K931044

Stantex Pty Ltd Oxiguard K914978

The Smart BiteBloc™ has the same intended use as the predicate devices identified in this section. Any technological differences with the predicate devices do not raise any new questions regarding safety and effectiveness. Therefore, Oridion considers the Smart BiteBloc to be substantially equivalent to the predicate devices.

PRODUCT CLASSIFICATION

73CCK Class II

21 CFR 868.1400, carbon dioxide analyzer

The BiteBloc™ itself is normally classified according to 21CFR876.1500 as follows:

Class I

Product Code MNK

INTENDED USE

The proposed device, Smart BiteBloc™, will be used during endoscopy procedures that require a bite block that enables and supports the convenient use of, and will not interfere with, an oral nasal cannula (K011536) for collecting samples of the patient's breathing to measure CO₂ with a capnograph while simultaneously administering supplemental oxygen near the nose for inhalation. It can be used for non intubated patients who weigh more than 55 lbs (25 kg).



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Sandy Brown
Regulatory Affairs Director
Oridion Medical 1987 Limited
7 Hamarpe Street
Jerusalem, 91450
ISRAEL

Re: K042665
Trade/Device Name: BiteBloc™
Regulation Number: 868.1400
Regulation Name: Carbon Monoxide Gas Analyzer
Regulatory Class: II
Product Code: CCK, MNK
Dated: September 27, 2004
Received: September 29, 2004

Dear Mr. Brown:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Modified Indications for Use Statement

This document is not confidential

November 11, 2004

Device Name:

BiteBloc™

Indications For Use:


The proposed device, Smart BiteBloc™, will be used during endoscopy procedures that require a bite block that enables and supports the convenient use of, and will not interfere with, an oral nasal cannula (K011536) for collecting samples of the patient's breathing to measure CO₂ with a capnograph while simultaneously administering supplemental oxygen near the nose for inhalation. It can be used for non intubated patients who weigh more than 55 lbs (25 kg).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K042665