K031118

# Annex 1- 510(k) Summary for IntraOs 70

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K030119

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| Date: | March 18, 2003 |
| Applicant | Blue X Imaging Srl.<br>Via Idiomi 3/16<br>20090 Assago – Milan – Italy<br>Phone: + 39-0245712171<br>Fax: + 39-0246703385 |
| Contact Person | Giuseppe Giacomini – CEO & General Manager |
| Device Name: | IntraOs 70 |
| Common Name: | X-Ray |
| Classification Name: | Unit, X-Ray, Extraoral |
| Legally Marketed device to which firm is claiming equivalence: | Explor-X 70 |
| Description of the Device: | IntraOs 70 is a Dental X-Ray generator; its primary use is for intra oral image receptor radiology. For such application, a peak voltage of 70 $kV_p$ has been demonstrated to give a high quality film with a good film quality/risk ratio.<br><br>The beam-limiting device is formed by a circular cone, which grants a source skin distance of 20cm and has a round output field of 6cm diameter. The weight of the tubehead is 6.4 kg. The certified components may be assembled in different configurations in terms of arms and mounting.<br><br>Exposure times are microprocessor controlled, assuring a high constancy and also repeatability. The operator may choose exposure times from 60 ms to 3,2 s by object selection. Manual setting possibility or exposure time from 60 ms to 3,2 s (plus or minus, 18 steps: 0.06; 0.08; 0.10; 0.12; 0.16; 0.20; 0.25; 0.32; 0.40; 0.50; 0.64; 0.80; 1.00; 1.25; 1.60; 2.00; 2.50; 3.20 s) if required. |

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| | Timer and hand switch can be remotely mounted. The hand-switch is provided with a 3 m-coiled cord. |
| Intended use of the device: | IntraOS 70 is an extra oral source X-ray system for dental radiographic examination and diagnosis of diseases of the teeth. |

Summary of the Technological characteristics of IntraOs 70 compared to the predicate device Explor-X 70

| | Explor-X 70 | IntraOs 70 |
|---|---|---|
| Intended Use | Extra oral source X-ray system for dental radiographic examination and diagnosis of diseases of the teeth | Extra oral source X-ray system for dental radiographic examination and diagnosis of diseases of the teeth |
| High Voltage value | 70 kVp | 70 kVp |
| Tube current | 8 mA | 7mA |
| Tube insert | CEI OCX 70-G | OCX 70-G / RF8G070 |
| H.V. type: | Single phase, self rectifying | Single phase, self rectifying |
| X-Ray exposure time control | Microprocessor Controlled | Microprocessor Controlled |
| Compensation of Line Voltage Fluctuations | Yes, automatically by software algorithm | Yes, automatically by software algorithm. This function can optionally be activated during installation. |
| Safety features | Dead man command Safety backup timer | Dead man command Safety backup timer |
| Signaling devices | Acoustic and visual signal Optional remote signaling | Acoustic and visual signal Optional remote signaling |

The main differences of the IntraOs 70 with respect to SE device are mainly aesthetics; the functionality and technology are similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 0 8 2003

Blue X Imaging Srl.
% Mr. Al Sosa
President
Chicago X-Ray Systems, Inc.
251 E. Dundee Road Suite #6
WHEELING IL 60090

Re: K031118
Trade/Device Name: IntraOs 70
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: March 18, 2003
Received: April 9, 2003

Dear Mr. Sosa:

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 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 one of the following numbers, based on the regulation number at the top of the letter:

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| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K031118
DEVICE NAME: IntraOS 70
INDICATIONS FOR USE:

The IntraOs 70 (with Autoset Timer) is intended for the dental radiographic examination and diagnosis of diseases related to the anatomical structures of the teeth. Such a device makes use of an extra oral source x-ray system commonly referred to as intraoral x-ray equipment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Formay 1-2-96)

David A. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031118