

## 510(k) SUMMARY

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

OCT - 6 2011

The assigned 510(k) number is: K111343

1. **Submitter's Identification:**

Crosstex International, Inc.  
10 Ranick Road  
Hauppauge, New York 11788  
Tel No.: 631-582-6777  
Fax No.: 631-582-1726

**Contact Person:**

Mr. Gary Steinberg  
President  
Crosstex International, Inc.  
10 Ranick Road  
Hauppauge, New York 11788  
Tel No.: 631-582-6777  
Fax No.: 631-582-1726

Date Summary Prepared: November 4, 2010

2. **Name of Device:**

- Crosstex® Isofluid Plus Surgical Earloop Face Mask – Blue
- Crosstex® Isofluid Plus FogFree Surgical Earloop Face Mask – Blue
- Crosstex® Isofluid Plus FogFree Surgical Earloop Face Mask with Splash Visor - Blue

3. **Predicate Device Information:**

Crosstex® Isofluid FogFree Earloop Face Mask

**4. Device Description:**

The Crosstex Isofluid Plus Surgical Masks are constructed of a cellulose inner facing, a 100% spunbonded polypropylene outer facing, a 100% meltblown polypropylene filter media, with non-latex elastic loops. The nose piece for the Crosstex Surgical Masks is aluminum wire while the no fog strip (if applicable) is made of melt blow polypropylene.

**5. Intended Use:**

The following Crosstex Isofluid Plus Surgical Masks are intended for use in infection control practices to minimize contamination caused by inhaled and exhaled microorganisms and reduce the potential exposure of the wearer to blood and body fluids.

- Crosstex® Isofluid Plus Surgical Earloop Face Mask – Blue
- Crosstex® Isofluid Plus FogFree Surgical Earloop Face Mask – Blue
- Crosstex® Isofluid Plus FogFree Surgical Earloop Face Mask with Splash Visor - Blue

**6. Comparison to Predicate Devices:**

Description	Crosstex Surgical Masks	Predicate Device: K082258
Outer Layer	Spunbond Polypropylene	Spunbond Polypropylene
Filter Media	Melt Blown Polypropylene	Melt Blown Polypropylene
Inner Layer	Cellulose	Spunbond Polypropylene
Nose Piece	Aluminum Wire	Aluminum Wire
Attachment	Earloop	Earloop
Anti-Fog (If Applicable)	Melt Blown Polypropylene	Melt Blown Polypropylene
Specifications and Dimensions	Same	7" x 3.5"
Mask Style	Same	Flat Pleated
Sterile	No	No
Single Use	Yes	Yes

Description	Crosstex Surgical Masks	Predicate Device: K082258
Fluid Resistance: ASTM 1862	32 of 32 pass at 80mm Hg	30 of 32 pass at 80mm Hg
Particulate Filtration Efficiency: ASTM F2299	99.01% at 0.1 $\mu\text{m}$	98.5% at 0.5 $\mu\text{m}$
Bacterial Filtration Efficiency: ASTM F2101	99.8%	99.8%
Flammability Class: 16CFR1610	1	1
Delta-P: Mil M36954C	2.5	2.86

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

- a. Fluid Resistance: Synthetic Blood Penetration Test
- b. Bacterial Filtration Efficiency (BFE) / Differential Pressure ( $\Delta\text{P}$ ) Tests
- c. Flammability Testing
- d. Latex Particle Challenge Test
- e. Biocompatibility Testing Per ISO 10993

It was our conclusion that Performance Testing met all relevant requirements of the aforementioned test standards.

8. **Discussion of Clinical Test Performed:**

Not Applicable

9. **Conclusions:**

The Crosstex® Isofluid Plus Surgical Masks have the same intended use and technological characteristics as the predicate device. Moreover, bench testing contained in this submission demonstrates that the technological characteristics do not raise any new questions of safety or effectiveness. The Crosstex® Isofluid Plus Surgical Masks are substantially equivalent to the predicate device.



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

Crosstex International, Incorporated  
C/O Mr. Richard M. Ormsbee  
Corporate Regulatory Affairs Manager  
Minntech Corporation  
14605 28<sup>th</sup> Avenue North  
Minneapolis, Minnesota 55447

OCT - 6 2011

Re: K111343  
Trade/Device Name: Crosstex<sup>®</sup> Isofluid Plus Surgical Masks  
Regulation Number: 21 CFR 878.4040  
Regulation Name: Surgical Apparel  
Regulatory Class: II  
Product Code: FXX  
Dated: September 20, 2011  
Received: September 21, 2011

Dear Mr. Ormsbee:

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" (21 CFR 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/ReportProblem/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,



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

## Indications for Use

510(k) Number (if known): K111343

Device Name: Crosstex® Isofluid Plus Surgical Masks

### Indications for Use:

The following Crosstex® Isofluid Plus Surgical Masks are intended for use in infection control practices to minimize contamination caused by inhaled and exhaled microorganisms and reduce the potential exposure of the wearer to blood and body fluids. (non-sterile)

- Crosstex® Isofluid Plus Surgical Earloop Face Mask – Blue
- Crosstex® Isofluid Plus FogFree Surgical Earloop Face Mask – Blue
- Crosstex® Isofluid Plus FogFree Surgical Earloop Face Mask with Splash Visor - Blue

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

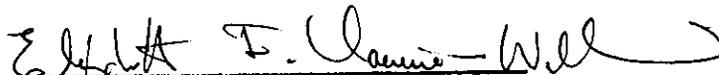
AND/OR

Over-The-Counter Use  X   
(21 CFR 801 Subpart C)

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NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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