SEP 23 1997

K972397

Intertex Research, Inc.

P.O. Box 90785

Houston, TX 77090

Non-Confidential Summary of Safety and Effectiveness

June 24, 1997

Intertex Research, Inc.
P.O. Box 90785
Houston, TX 77090 Tel - 281-537-5388

Official Contact:	John Bullock, Ex. Vice President
Proprietary or Trade Name:	EZ Spray
Common/Usual Name:	Powered atomizer
Classification Name:	Nebulizer, medicinal, non-ventilatory (atomizer)
Device:	EZ Spray
Predicate Devices:	DeVilbiss Atomizer Model 5005 - preamendment

Device Description:

The disposable, air or gas powered venturi sprayer / atomizer with reservoir and spring loaded flow control button, with an adjustable spray nozzle.

Indicated Use --	A disposable, nose or throat atomizer for either oil or water base solutions.
Environment of Use --	Hospital, Operating Room (OR), ICU, anesthesia or physician office.
Patient population --	Patients requiring a nasal or throat lavage.

Comparison to Predicate Devices:

Attribute	EZ Spray	DeVilbiss Atomizer
Use		
Intended for lavaging nose and throat	Yes	Yes
Atomizing oil and water base solutions	Yes	Yes
Environment of use - Hospital, OR, anesthesia, ICU, physician office	Yes	Yes
Disposable	Yes	No

Attribute	EZ Spray	DeVilbiss Atomizer
Design / Theory of Operation		
Venturi design for atomizing solution	Yes	Yes
Utilizes air or oxygen to atomizer solutions	Yes	Yes
Adjustable tip to direct spray up or down	Yes	Yes
Available to adjust flow / output	Yes	Yes
Method of adjusting flow	Spring loaded button	Opening which is manually covered
Reservoir bottle	Yes	Yes
Connection port for air source	Yes	Yes
Materials		
Bottle	Polycarbonate	Glass
Nozzle assembly	ABS	Metal
Performance Standards / Specifications		
Gas or air source is dry, compressed air or oxygen	Yes	Yes
Plume geometry generally concial	Yes	Yes
Operating pressure and flow 10 Lpm @ 50 psi	Yes	Yes
Delivers a volume of at full flow in 60 seconds	1.9 oz	2 oz
Differences between Other Legally Marketed Predicate Devices		

There is no differences between the intended device and the predicate device which would be significant to patient safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1997

Mr. John Bullock
Intertex Research, Inc.
P.O. Box 90785
Houston, Texas 77090

Re: K972397
EZ Sprayer
Regulatory Class: I (one)
Product Code: 73 CCQ
Dated: June 24, 1997
Received: June 26, 1997

Dear Mr. Bullock:

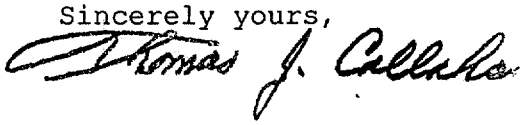
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 3

INDICATIONS FOR USE

Pursuant to the Notice of February 6, 1996 regarding listing of Indications for Use on a separate sheet, the following is per that request.

510(k) Number: K972379

Device Name: EZ Spray

Indications for Use: EZ-Sprayer is intended to apply topically by spray or atomizing an oil or water base solution to either the nose and / or throat, for example, topical anesthetics solutions of lidocaine or xylocaine.

The device will not be supplied with water or oil base solutions.

Contraindications: Not intended for use for Meter Dose Inhalation agents such as bronchial dilators and inhaled steroids.

Environment of use: Hospital (Anesthesia, ICU, OR, Cath Lab, Endoscopy, Cardiology, Pulmonolgy, Burn units, General patient wards), physician offices and home care .

Patient Population: Child to adults

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use ✓ **or** **Over-the-counter use** __
(Per CFR 801.109)