

SEP 12 2011

**510(k) SUMMARY**

**510(k) NUMBER:** K112400

**SUBMISSION TYPE:** Traditional

**SUBMITTED BY:** Medix, Inc.  
230 A1A North  
Ponte Vedra, FL 32082  
Tel: 904-382-8026  
Fax: 866-871-3721

**CONTACT PERSON:** Dan Quiggle  
President & CEO

**DATE OF PREPARATION:** June 1, 2011

**NAME OF DEVICE:** SmartShears®

**CLASSIFICATION NAME:** Surgical Devices; General and plastic surgery  
(Regulation Number 21 CFR 878.4800[FZT])

**TRADE NAME:** Lister Bandage Scissors

**PREDICATE DEVICE(S):** Conphar, Inc. (K821116)

**INDICATIONS FOR USE:** SmartShears® is a manual surgical instrument intended to be used in removing bandages, splints, and clothes in trauma situations.

**DEVICE DESCRIPTION:** SmartShears® is a 4-in-1 device used for the removal of bandages, splints, and clothes. The device consists of four configurations which include: the trauma shears, ruler, angle and reflex hammer.

*Shears:* Critical to the development of the SmartShears® for the cutting of bandages, splints or clothes

*Ruler:* The ruler is used for measuring the length of lacerations and the size of entrance/exit wounds, location of a fracture, and rash size.

*Angle:* The angle can be used to measure for angulation of bone fractures.

*Reflex Hammer:* The reflex hammer can be used during a reflex procedure when the cutting blades are closed for testing tendon reflexes and percussing both the abdominal and chest.

**PREDICATE DEVICE:** The SmartShears® are essentially the same as the previously marketed predicate device in both function and indication of use. The SmartShears® and the listed predicate device Conphar, Inc. Lister Bandage Scissors (K821116) are similar in size with overall length and scissor blades (5 1/2"). The device utilizes the same material made up of medical grade stainless steel materials.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WC066-G609  
Silver Spring, MD 20993-0002

NuScience Consulting and Management Group, LLC  
% Ms. Nikole Goldsmith  
PO Box 8507  
Fleming Island, Florida 32006

SEP 12 2011

Re: K112400  
Trade Name: SmartShears®  
Classification Regulation Name and Number: Manual surgical instruments for  
general use - 21 CFR 878.4800  
Regulatory Class: Class I Exempt  
Product Code: FZT  
Dated: June 1, 2011  
Received: August 19, 2011

Dear: Ms. Goldsmith:

We have reviewed your premarket notification submission and have found this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). Therefore, you may immediately begin marketing this device as described in your premarket notification.

The final classification regulation for your device appears in Title 21 of the Code of Federal Regulations (CFR) 878.4800. We suggest that you review this regulation since it may grant other exemptions from certain general controls of the Act. Your device classification regulation name, regulatory class, and product code are shown above. When listing your device with the Food and Drug Administration, please use this product code.

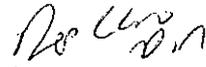
In the future, new but substantially equivalent devices which fall within the above classification regulation name and meet the classification criteria may be marketed without sending a premarket notification submission to the Food and Drug Administration. We suggest, however, that you review 21 CFR Section 878.9 to determine whether or not your new device (s) meets the limitations of exemption from Section 510(k) of the Act.

If you have any questions regarding this letter, please contact Dwight Yen (301) 796-6401 or 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/DeviceRegulationandGuidance/ucm142656.htm>".

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health



## Indications for Use

510(k) Number (if known): K112400

Device Name: SmartShears®

Indications For Use: SmartShears® is a manual surgical instrument intended to be used in removing bandages, splints, and clothes in trauma situations.

Prescription Use   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Lyden for mcm  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

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