SEP 1 2 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®

CLASSIFACTION 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 DESRIPTION: 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-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 X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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