CONCORD PORTEX

K923127

APR 29 1993

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary Needle-Pro™ Cartridge

Date: June 24, 1992

Device Name trade or proprietary:
Needle-Pro™ Cartridge.

Device Name common or classification:
Hypodermic Needle single lumen needle.

Device to which this device is substantially equivalent:
Hypodermic Needle single lumen needle and Needle-Pro™.

Description of Device:
The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub designed to mate with a male connector (nozzle) of a poison syringe or an intravascular administration set. There is a needle protection device attached that may be placed over the needle and snapped on after the needle has been used.

Proposed and Intended Use:
To inject into or withdraw fluids from, parts of the body below the surface of the skin. This device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set. There is a needle protection device (Needle-Pro™) attached that may be snapped over the needle after the needle has been used.

Technical characteristics:
These products are standard products that are on the market and manufactured from stainless steel for the cannula and the plastic parts are made of poly propylene. The needles and the Needle Pro™ are commercially available now and both have approved 510Ks. The needles are approved with 510K number K85457A and the Needle Pro™ is approved under 510K number K 904198. These products are safe and effective as approved. This application was to allow the two parts to be sold as a unit as Concord/Portex has not previously sold needles for this purpose. Needle-Pro™ and Needle-Pro™ S have a shoulder added to stake the needle sheath to them. A shoulder was also added to the female end to allow a cap to be staked onto it. This product will be packaged in various quantities for customer convenience.

Concord/Portex.
Sincerely,

Robert Wheeler
Director of Regulatory Affairs
K/NPC

CONCORD/PORTEX, 15 Kit Street, P.O. Box 724, Keene, N.H. 03431-0724, Tel: 603/352-3812, Fax: 603/352-3703

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 14, 2015

Concord Portex
Robert Wheeler
Director of Regulatory Affairs
15 Kit Street, P.O. Box 724
KEENE, NEW HAMPSHIRE, 03431

Re: 510(k) NUMBER: K923127
Trade/Device Name: NEEDLE-PRO™ CARTRIDGE
Regulation Number: 21 CFR 880.5570
Regulation Name: NEEDLE, HYPODERMIC SINGLE LUMEN
Regulatory Class: Class II
Product Code: FMI
Date: April 12, 1993
Received: April 13, 1993

Dear Mr. Wheeler:

This letter corrects our substantially equivalent letter of April 29, 1993.

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/ReportaProblem/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 Industry and Consumer Education 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,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure]