K060002

JUN - 2 2006

North Sydney
NSW 2060 Australia

www.ritract.com

510(k)
PREMARKET NOTIFICATION
SUMMARY

1. **Submitter Details:**

Ritract Limited
ABN 28 106 353 253
Level 17, 201 Miller Street
North Sydney, NSW 2060
Phone: +61 2 8923 2512

2. **Contact Person:**

Mr. Rupert Northcott
Managing Director, Ritract Limited
Level 17, 201 Miler Street
North Sydney, NSW 2060
Australia

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Email: rupert@ritract.com

3. **Name of the device**:

Proprietary Name: Ritract Safety Syringe
Common/Usual Name: Syringe Hypodermic
Classification Name: Piston Syringe

4. **Predicate Device(s):**

- BD Integra Spring Based Syringe K011103
- Nipro Disposable Syringe K030683

5. Device Description

The Ritract Safety Syringe is a sterile, single-use, disposable, non-reusable, 3mL, 5mL, 10ml, auto-retracting safety syringe with a standard luer lock needle connection.

6. Indications for Use:

The Ritract Safety Syringe is a sterile, single-use, disposable, non-reusable, auto-retracting safety syringe which is intended for injection of fluids into the body, while reducing the risk of sharps injury and the potential for syringe reuse.

7. Summary of the technological characteristics of our device compared to the predicate device:

The Ritract Safety Syringe operates in the same fashion as the BD Integra 3ml Syringe. The needle is assembled by the user onto the syringe, the user draws the required fluid into the barrel as indicated by the graduation marks by drawing back the plunger, and the user injects the fluid by pushing the plunger forward till it bottoms out in the barrel. In both devices when the plunger bottoms out in the barrel this action activates a simple mechanism which releases the compressed spring and draws the needle back up into the barrel of the syringe with no protrusion of the syringe tip from the device.

In the case of the BD Integra Syringe the mechanism which releases the compressed spring is as follows: The plunger contains a tool which as it bottoms out in the barrel travels through the piston seal and pierces a hub on the dedicated BD Integra Needle which releases the spring drawing the needle fully up inside the plunger.

The Ritract Safety Syringe also uses the action of the plunger bottoming out to release the compressed spring. In the case of the Ritract Syringe the spring is held in compression by a collar system which as the plunger bottoms out the interaction of the plunger profile and the collar activates the release of the spring and draws the needle into the barrel of the syringe with no protrusion of the needle tip from the device.

8. Equivalence

The Ritract Safety Syringe is substantially equivalent to the BD Integra Syringe in terms of the mode of operation, function, materials used, packaging, manufacturing processes and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2006

Mr. Rupert Northcott
Managing Director
Ritract, Limited
Level 17, 201 Miller Street
North Sydney, NSW 2060
AUSTRALIA

Re: K060002
Trade/Device Name: Ritract Safety Syringe
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: May 12, 2006
Received: May 16, 2006

Dear Mr. Northcott:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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 Statement

510(k) Number (if known):

K060002

Device Name:

Ritract Safety Syringe

Indications for Use:

The Ritract Safety Syringe is a sterile, single-use, disposable, non-reusable, auto-retracting safety syringe which is intended for injection of fluids into the body, while reducing the risk of sharps injury and the potential for syringe reuse.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use__X___ OR Over-The-Counter Use___
(Per 21 CFR 801.109) (Optional Format 1-2-96)

...ion Sign-Off)
...ion of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...) Number: K060002