K973888

JUN 3 1998

510(k) Summary

1. Applicant

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2. Device Details

Syringe Trade Name:	Smartlock™
Common Names:	hypodermic syringe, safety syringe, piston syringe with safety mechanism
Classification Name:	piston syringe
Class:	II

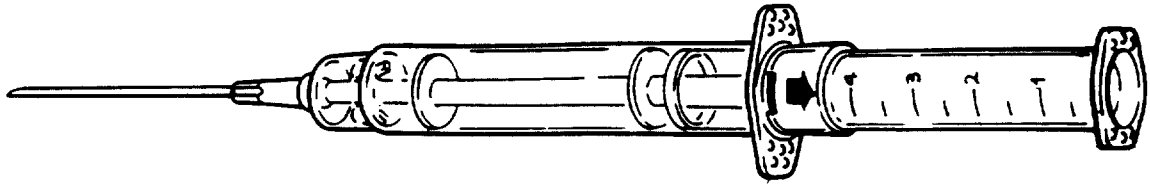
3. Predicate Devices

The Smartlock™ safety syringe is substantially equivalent to the Becton Dickinson Plastipak™ standard syringe in use.

The Smartlock™ safety syringe is also substantially equivalent to the Becton Dickinson Safety-Lok™ safety syringe

4. Product Description

The Smartlock™ safety syringe is a sterile, single use hypodermic syringe incorporating an innovative safety mechanism. It is designed to withdraw the needle into the safety shield after use and to lock it in this position.



Smartlock™ Safety Syringe - 5ml

The Smartlock™ safety syringe is a slight departure from standard syringes in that whilst it consists of three parts i.e. a safety shield, a barrel and a plunger, there are differences in their design. There is no rubber piston. The syringe is packaged fully assembled and no set-up action or pre-use motion is necessary. Needles are attached in the standard luerslip method and can be changed during a procedure, if necessary. The materials used in production are medical grade polypropylene and polyethylene.

As the last of the medication is delivered, the plunger rim will disengage the safety clips from the shoulder. As the plunger is retracted (as if to refill), the needle will also retract. The plunger must be retracted fully until a "click" sound is heard and no movement is possible. Disposal is then simple and safe. The functioning of the 3ml, 5ml and 10ml Smartlock™ Safety Syringes are identical in all respects, save the amount of fluid which can be aspirated.

5. Intended Use

The Smartlock™ safety syringe is intended as a sterile, single use, disposable syringe to be used for injecting medications or fluids into the patient by attached cannula or via intravenous therapy, or to draw samples or fluids by the same means. Only once the medication has been administered or the sample taken, should the safety mechanism be activated.

The intention of the safety mechanism is, after use of the syringe, to bring the needle within the safety shield in one motion and to lock it in that position, rendering the syringe unusable. The safety mechanism has no effect on the efficacy of the syringe in regard to its performing the function of a standard syringe. The 3ml, 5ml and 10ml Smartlock™ syringes all function using the same principle and all have the same intended use.

The Smartlock™ syringes are not intended to be used with syringe pumps. The appropriate warnings are printed on the syringe labeling.

6. Comparison

COMPARISON OF SYRINGES

COMPARISON	*Smartlock™ SAFETY SYRINGE*	*B-D SAFETY-LOK™*	*B-D PLASTIPAK™*
Syringe Size	5ml - single use	5 ml - single use	5ml - single use
Syringe Type	Safety	Safety	Standard
Number of Parts	3	6	3
Materials	Safety shield and Plunger – Polypropylene Barrel – Polyethylene All components silicone free	Plunger, Barrel, Safety shield, Locking Ring - Polypropylene Piston - Silicone Rubber	Plunger and Barrel - Polypropylene Piston - Silicone Rubber
Connection Type	Luerslip	Luerlock	Luerlock
Scales and Markings	Graduations as per ISO 7886 with scale intervals of 0.5ml. Blue indicator arrow at base of safety shield. All graduations can be clearly read. Use once only. Trademark symbol	Graduations as per ISO 7886with scale intervals of 0.2ml. Green strip around safety shield. Graduations can only be read through the safety shield. Sterile single use. Trademark symbol.	Graduations as per ISO 7886 with scale intervals of 0.5ml. Graduations can be clearly read. Trademark symbol.
Color	Parts - virgin material (clear) Printing - blue	Parts - virgin material (clear) - red locking ring Printing - black and green	Parts - virgin material (clear) Printing - black
Safety Feature	Needle retracts into safety shield and locks in one operation. Mechanism activated manually on dispensing of medication.	Safety shield is pulled over needle and locks in one operation. Mechanism activated manually on dispensing of medication.	No safety feature.

Numbering	Read in reverse off plunger.	Read forward off barrel.	Read forward off barrel.
Aspiration	Fluid fills into the plunger as the plunger is withdrawn.	Fluid fills into the barrel as the plunger is withdrawn.	Fluid fills into the barrel as the plunger is withdrawn.
Volume Determination	Read off the arrow indicator at the base of the safety shield.	Read off the top edge of the black rubber piston.	Read off the top edge of the black rubber piston.
Warnings	Not to be autoclaved. Not suitable for blood gassing. Only to be used with needles 1½" or shorter. Not to be used with syringe pumps.	Not to be autoclaved. Only to be used with needles 1½" or shorter. Not to be used with syringe pumps.	Do not re-sterilise. Not to be used with paraldehyde.
Intended Use	As a single use, hypodermic syringe. Safety feature protects after administration.	As a single use, hypodermic syringe. Safety feature protects after administration.	As a single use, hypodermic syringe. No safety feature.
Operation	**6 steps to operate :** 1. attach needle / remove needle cap 2. draw medication 3. expel air 4. administer medication 5. pull to lock safety mechanism 6. dispose	**6 steps to operate :** 1. attach needle / remove needle cap 2. draw medication 3. expel air 4. administer medication 5. pull to lock safety mechanism 6. dispose	**5 steps to operate :** 1. attach needle / remove needle cap 2. draw medication 3. expel air 4. administer medication 5. dispose
Re-usability	Cannot re-use	Cannot re-use	Easy to re-use
Sterilisation	EO gas (non-flammable)	Gamma radiation.	EO gas.
Labeling	1. On primary syringe packaging 2. On dispensing box	1. On primary syringe packaging 2. On dispensing box	1. On primary syringe packaging 2. On dispensing box

7. Clinical Trial

Clinical trials were held in three South African hospitals to compare the Smartlock™ safety syringe to the Becton Dickinson Plastipak™ standard syringe. The primary hypothesis was that the Smartlock™ safety syringe would be substantially equivalent to the conventional syringe in respect of comparable characteristics.

The information collected was comprehensive and extremely detailed and included both the objective and subjective experiences of the participating nurses. Monitoring of the actual use of syringes by the nurses, was by experienced personnel and evaluation of the number of syringes which functioned successfully was by an independent auditor.

The results were largely clear cut. The nurses ranked both types of syringes similarly and positively, and this was confirmed by the monitors and the auditor. The Smartlock™ safety syringe proved substantial equivalence to the Plastipak™ syringe in use.

8. Simulated Use Study

A simulated use study was conducted at three separate American hospitals. The Smartlock™ safety syringe was compared to the Becton Dickinson Safety-Lok™ safety syringe. The success rates in correctly using the Smartlock™ safety syringe did not significantly differ from the rates seen with the Becton Dickinson Safety-Lok™ safety syringe among nurses who received instruction from the package insert. When a verbal "in-service" training session was added, the Safety-Lok™ was scored at a slightly higher level.

The study documented that the Smartlock™ safety syringe is substantially equivalent to the Safety-Lok™ safety syringe with respect to the rates of correct usage. The study also documented that "in-service" training sessions prior to introducing the syringes to hospitals would enhance the rate of correct usage.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Medical Innovation Limited
C/O Mr. Daniel A. Kracov
Counsel to Medical Innovations Limited
Patton Boggs, L.L.P.
2550 M Street N.W.
Washington, DC 20037-1350

Re: K973888
Trade Name: Smartlock Safety Syringe
Regulatory Class: II
Product Code: MEG
Dated: March 31, 1998
Received: March 31, 1998

Dear Mr. Kracov:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Smartlock™ Safety Syringe

Indications For Use:

A sterile, single-use hypodermic syringe, incorporating a safety mechanism designed to withdraw the needle back into the safety shield after use and lock it in this position. To be used for injecting medications or fluid into the patient by attached cannula or via IV therapy or to draw samples or fluids by the same means.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rebecca Cosgrove

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K973888

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)