

510(k) Number (if known): K972452

Device Name: RAMY PISTON SYRINGE

Indications For Use:

Single use piston syringe used to inject fluids into the body. The device has an integrated attached needle and can be sold for prescription or non-prescription use. The tuberculin syringe is for prescription use and the insulin syringe can be sold for non-prescription use. The syringes are sold sterile and are also non-pyrogenic and non-toxic.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Fabiana Cuervo
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972452

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use Insulin

510(k) Number (if known): K971664

Device Name: RAMY Piston Syringe

Indications For Use:

General purpose single use piston syringe used to withdraw or inject fluids into the body. The device is sold as sterile with attached needle and is non-pyrogenic. The device is not intended for use with any specific drugs or biologics. It is sold as a prescription device with needle attached and ready for use.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) *Patricia Curran*
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971664

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)