K991680

JUN 3

510(k) Summary of Safety and Effectiveness as required by 21 CFR 807.92©

1. **Submitted by:** Androsystems srl
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3. **Date Summary Prepared:** April 26, 1999

4. **Device Name:** Common or Usual Name: auto-injector
Proprietary and Trade Name: SOFTINJECT
Classification Name: Syringe needle introducer per 21 CFR 880.6920

5. **Predicate Device:** ID-300, 510(k) number K961309
Pos-T-Vac, Inc.
1701 N. 14th Ave.
PO Box 1436
Dodge City, KS 67801

6. **Description of Device:**

The SOFTINJECT is a syringe needle introducer, commonly known as an auto-injector. It is made of plastic molded parts and springs. The spring-loaded mechanism provides an injection with a hypodermic needle to a pre-determined depth below the skin surface.
The SOFTINJECT is intended to be used with FDA-approved B-D 1 ml insulin syringes and approved needles filled with FDA-approved pharmaceutical products.
The SOFTINJECT has been designed to assist in the subcutaneous or intracorpus cavernosa injection of pharmaceutical products.

7. **Intended Use:**

The SOFTINJECT is an auto-injector indicated for assisting in the subcutaneous or intracorpus cavernosa injection of approved pharmaceutical products with approved commercially available syringes and needles.

8. Comparison with Predicate Device

The SOFTINJECT is substantially equivalent to the Pos-T-Vac auto-injector, the ID-300, which was cleared by FDA on 10 June 1996 (K961309).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 1999

Dr. Ermanno Greco
Marketing Director
Androsystems srl
Viale Liegi, 12
00198 Roma, Italy

Re: K991680
Trade Name: SOFTINJECT®
Regulatory Class: II
Product Code: KZH
Dated: April 26, 1999
Received: May 17, 1999

Dear Dr. Greco:

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: SOFTINJECT

Indications For Use:

The SOFTINJECT is an auto-injector used for the subcutaneous and intracorpus cavernosa injections at predetermined depths of approved pharmaceutical products with approved commercially available syringes and needles.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucanta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K99 4680

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