MAR - 6 2001

510(k) Summary
(As required by 21 CFR 807.92(a))

A. Submitter Information

Equidyne Systems Inc.
11770 Bernardo Plaza Court, Suite 351
San Diego, CA 92128

Phone Number: 858-451-7001
Fax Number: 858-451-7002
Contact: Jim Barley
Regulatory Affairs
Date: December 12, 2000

B. Device Information

Trade/Proprietary Name: Injex 50 Needle Free Injection System

Common name of device: Jet Injector

Classification Name: Injector, Fluid, Non-Electrically Powered

C: Predicate Device: Hypex Jet Injector

Predicate 510(k) #: K945873

D. Device Description:

Equidyne Systems Injex 50 Injector System is a means of administering subcutaneous medications without the use of needles. The needle free injector utilizes a high velocity focused jet of liquid to penetrate the skin and deposit the medication in the subcutaneous tissue. The process takes place in a fraction of a second. Needle free injection is useful in a wide range of drug therapy including immunization vaccines, hormones and local anesthetics, as well as the administration of insulin to the diabetic population, where individuals may need a number of injections per day.

D. Device Description: (cont.)

The Injex 50 Injector system consists of four main components;

1. Injector - A small re-usable hand held Injector,
2. Reset Box - A compact re-usable Reset Box used to reset and store the Injex 50 Injector,
3. Ampule - A disposable, sterile 0.5 ml Ampule that functions like a needle syringe to draw the medication from the medicine bottle or vial using a hand draw with a plunger. Once the Ampule is loaded into the Injex 50 Injector, the dose is injected into the individual by releasing the Safety and pressing the trigger.
4. Vial Adapter - A disposable, sterile Vial Adapter facilitates the transfer of the medication from the medicine bottle or vial to the Ampule.

The Injex 50 Injector can deliver variable doses of fluid medication from 0.15 ml to 0.50 ml.

E. Intended Use:

The Injex 50 Injector System is designed to deliver various medicines and vaccines by means of a narrow, high velocity jet of fluid which penetrates the surface of the skin and delivers the medicine or vaccine to the body.

F. Comparison of Required Technological Characteristics:

The Injex 50 Injector System has the same technological characteristics as the Hypex Jet Injector. The key differences between the two devices is the spring tension.

G. Summary and Conclusion of Nonclinical Tests

Biocompatibility

The ISO-FDA Modified Matrix, FDA/ODE General Program Memorandum - # G95-1 was reviewed to determine applicable biocompatibility tests. In addition to the raw material testing by the supplier, Equidyne Systems conducted a Cytotoxicity Study using the ISO Agarose Overlay Method and ISO Skin Irritation Study in the rabbit on the sterilized Ampule material.

G. Summary and Conclusion of Nonclinical Tests

Biocompatibility (cont.)

Following is a summary of all test results:

| BIOCOMPATIBILITY TEST | TYPE | RESULT |
|---|---|---|
| Cytotoxity | Agarose Overlay | Non toxic |
| Irritation and Sensitization | Primary Skin Irritation | Non irritating |

Equivalency Tests

The purpose of the equivalency testing was to show that the Injex 50 Injection System is safe and effective for its intended use and that an injection from the Injex 50 Injector is substantially equivalent to that of the predicate device.

The chicken breast was used as a human subcutaneous tissue model due to its similarity to human tissue. Chicken breasts were injected with 0.20 ml of colored water using both the Injex 50 Injector and the equivalent device. The injection sites were then dissected and the flow and dispersion of the colored water was examined and compared.

Results and Conclusion

The objective of this study was to show that the Injex 50 Injector System is safe and effective for its intended use and is substantially equivalent to the predicate device.

The results of testing showed that the flow and dispersion of the injected fluid from the Injex 50 Injector System was substantially equivalent to that of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2001

Mr. Jim Barley
Regulatory Affairs
Equidyne Systems, Incorporated
11770 Bernardo Plaza Court
San Diego, California 92128

Re: K003864
Trade Name: Injex 50 Needle Free Injector System
Regulatory Class: II
Product Code: KZE
Dated: December 12, 2000
Received: December 13, 2000

Dear Mr. Barley:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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" (21CFR 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/dsma/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): K003864

Device Name: Injex 50 Needle Free Injector System

Indications for Use:

The Injex 50 Needle Free Injector System is designed to deliver various medicines and vaccines by means of a narrow, high velocity jet of fluid which penetrates the surface of the skin and delivers the medicine or vaccine to the body.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K003864

(Optional Format 3-10-98)