K024018

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JAN 17 2003

avant
MEDICAL CORPORATION

SUMMARY OF SAFETY AND EFFECTIVENESS

AVANT MEDICAL CORPORATION

Avant Guardian™ 101

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Company:	Avant Medical Corporation 3914 Kendall Street San Diego, CA 92109 Tel: (858) 273-3674 Fax: (858) 274-6744
Company Representative:	John B. Slate, Ph.D. Sr. Vice President, Operations
Date 510(k) Prepared:	3 December 2002
Device Name:	Avant Guardian™ 101
Common Name:	Needle-free injection system
Classification Panel:	General Hospital
Classification Name:	Nonelectrically Powered Fluid Injector
Product Code:	KZE
CFR Section:	880.5430
Classification:	Class II

Devices to Which Substantial Equivalence is Claimed:

Avant Guardian™ 101 is substantially equivalent to the following currently marketed jet injectors:

- Bioject Biojector 2000 (K960373, K920631)
- Medi-Ject Vision (modification of the Medi-Ject Choice, K962956 and K994384)
- Equidyne Injex 30 (K945873)

Device Description:

The Avant Guardian™ 101 allows a medication or vaccine to be injected subcutaneously without the use of a needle. The system is designed to mimic the best clinical practices for injecting medications, namely, a slow injection of medication into tissue that is not compressed.

The product consists of a single-use medication reservoir (syringe) and a reusable injector. The operator employs an off-the-shelf vial adapter to fill the single-use medication reservoir with medication. The injector device is reset by compressing the spring-loaded push-rod. The medication reservoir is then placed in the Avant injector, which has an integral, battery-operated vacuum source. The patient places the reservoir against his skin and activates the vacuum by depressing the safety switch. To prevent an accidental discharge, the safety switch must be depressed and held until the injection is initiated by the operator depressing the inject button. As the vacuum is formed, skin is drawn up to and securely held in contact with the reservoir tip. Suction generated by the injector stabilizes the reservoir against the patient's skin to create a subcutaneous pocket (thereby avoiding muscle), eliminating the need to force the injector against the skin and compress the underlying tissue. The suction creates a seal around the tip that allows slow delivery of the medication, and stabilizes the device to prevent lacerations and movement of the orifice.

The medication is delivered in two stages. The patient depresses the inject button, causing a mechanism in the device to impact the medication reservoir plunger. Initially a high pressure, high speed jet of medication exits the reservoir orifice, puncturing the skin and the underlying tissue. The injection force quickly falls to a low level as the spring-loaded mechanism forces the medication into the subcutaneous tissue. The injector automatically stops the vacuum pump at the end of the injection, thereby indicating when the injector can be removed from the skin.

Intended Use:

The Avant Guardian™ 101 is designed to deliver various liquid medications and vaccines by penetrating the skin with a high-speed fluid jet and delivering the medication or vaccine to the underlying subcutaneous tissue.

Summary of Technological Characteristics Compared to Predicate Devices:

Extensive design verification, functional and performance testing have been conducted on the Avant Guardian™ 101 to demonstrate its ability to safely and effectively deliver injections similar to currently marketed jet injectors. The Avant Guardian™ 101 successfully completed the following tests:

- Biocompatibility testing per ISO 10993 requirements
- Design verification tests to confirm product integrity
- Side-by-side performance testing using a tissue model and simulated skin test chamber
- Risk analysis

The results indicate that the Avant Guardian™ 101 presents no new issues of safety when compared to the predicate devices.

The sponsor believes that the data submitted for the Avant Guardian™ 101 constitutes valid scientific evidence to support safety and effectiveness. The sponsor believes that the Guardian is safe and effective when used according to the device labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2003

Dr. John B. Slate
Avant Medical Corporation
3914 Kendall Street
San Diego, California 92109

Re: K024018
Trade/Device Name: Avant Guardian™ 101 Needle Free Injection System
Regulation Number: 880.5430
Regulation Name: Nonelectrically Powered Fluid Injector
Regulatory Class: II
Product Code: KZE
Dated: December 3, 2002
Received: December 4, 2002

Dear Dr. Slate:

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 (301) 594-4618. 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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

510(k) Number (if known): _____

Device Name: Avant Guardian™ 101 needle free injection system

Indications For Use:

The Avant Guardian™ 101 is designed to deliver various liquid medications and vaccines by penetrating the skin with a high-speed fluid jet and delivering the medication or vaccine to the underlying subcutaneous tissue.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

510(k) Number: K024018