

OCT 30 1998

K 983067

510(K) Summary / Statement

Submitters Name:

HENKE- SASS, WOLF GmbH

Kronenstrasse 16

D-78532 Tuttlingen Germany

Ph: (011) 49-7461-189-118 Fax: (011) 49-7461-189-182

Contact Name:

Ellen Henke, Official Correspondent for Submission

Wayne Knupp, Jr., Director Sales & Marketing-HENKE SASS WOLF

Stefan Knefel; Sales Manager Disposables HENKE SASS WOLF, GmbH

Name of Device:

Hypodermic Single Lumen Needle

SAFETY & EFFECTIVENESS DATA SUMMARY

Classification Name: Hypodermic Single Lumen Needle

Common/Usual Name: Hypodermic Needle

Proprietary Name: FINE-JECT®

Classification: Class II Hypodermic Single Lumen Needle # 80 FMI Reg. # 880.5570

Performance Standards: Devices are manufactured according to cGMP's, Applicable Harmonized Standards ISO 9001/EN 46001, applicable AAMI and ASTM Standards.

Material Composition: **Needle:** Surgical grade Stainless Steel (AISI SUS 304) certified according to ISO 5832/1 and ASTM 899, **Needle Hub:** Polypropylene/Novollen 1100N - From BASF; **Needle Protective Cap:** HDPE Mobil HMA 018 - From Mobil International, KL.

Intended Use: They are intended to be used for the purpose of injecting fluids into, or withdrawing fluids from parts of the body below the surface of the skin.

Sterilization Information : The HENKE-SASS ,WOLF Hypodermic Needles shall be distributed Sterile and are intended for single use only. Each Device, whether provided individually or contained in a set, will be sealed within a unit package to preserve sterility. The proposed device will be sterilized in a microprocessor - controlled ethylene oxide sterilizer at an ISO Approved Facility. Management review of sterilization results shall be conducted. Release of each lot will be contingent upon management approval of the related data and upon successful completion of sterilization verification results. All product shall be validated according to the current approved and published AAMI/ISO Standard: ISO 11135-1194 - "Medical Devices - Validation and routine control of ethylene oxide sterilization - Requirements". The product also complies with the European Norm - EN 550.

Device Description: The HENKE -SASS ,WOLF FINE-JECT® Disposable Needles are sterile hypodermic Single Lumen Needles, packaged individually for single patient use. The HENKE SASS WOLF Needles have the same operating principals and intended uses as the predicate devices already in commercial distribution

Predicate Devices: Becton Dickinson and Company "BD PrecisionGlide® Needle", TSK STERIJEKT Premium Disposable Hypodermic Needle, B. Braun STERICAN® Needles.

Comparison of Technological Characteristics: The Stainless Steel Material is identical to the predicate devices. The plastic hub material is identical to the predicate devices. The range of sizes available is similar to the predicate devices. In function, the needles are the same as the predicate devices with the same intended use.

Safety and Efficacy Information: The HENKE SASS WOLF Hypodermic Disposable Needles have the same operating principals and intended uses as those of the competitive devices already in commercial distribution.



OCT 30 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Ellen J. Henke
Official Correspondent for 510(k) Submission of Hypodermic
Single Lumen Needle
HENKE SASS WOLF of AMERICA, Incorporated
Soroco Industrial Park, Route 131
529 Ashland Avenue
Southbridge, Massachusetts 01550

Re: K983067
Trade Name: FINE-JECT®
Regulatory Class: II
Product Code: FMI
Dated: August 31, 1998
Received: September 2, 1998

Dear Ms. Henke:

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.

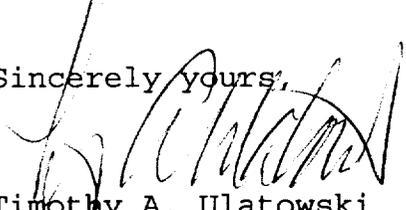
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2 - Ms. Henke

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: Hypodermic Single Lumen Needle

Indications For Use:

The Henke-Sass Wolf, Disposable Hypodermic Single Lumen Needle is intended to be used for the purpose of injecting fluids into, or withdrawing fluids from parts of the body below the surface of the skin.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucurita

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

510(k) Number K983047

Prescription Use
under 21 CFR 801.109)

OR

Over-The-Counter Use _____