SEP 2 0 2002

K022099

HDC Corporation's Safe-T-Peel® Safety Needle/Introducer 510(k) Summary

Name of Device Safe-T-Peel® Safety Needle/Introducer

Common or Usual Name Safety Needle/Introducer

Classification Names Catheter, Intravascular (Therapeutic, Short-term less than 30 days) - 21 C.F.R. §880.5200

Product Codes FOZ

Submitter

HDC Corporation
628 Gibraltar Court
Milpitas, CA 95035

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Contact Person: Earl Smart
Date Prepared: June 27, 2002~~June 26, 2002~~

Predicate Devices

Becton Dickinson Infusion Therapy Systems, Inc.	TFX Corporation	TFX Corporation
INTROSYTE Autoguard Shielded Introducer	TFX Medical Introducer Assembly	TFX Medical Safety Needle with Introducer
(K013304)	(K993191)	(K000665)

Intended Use

The Safe-T-Peel® Safety Needle Introducer is used to facilitate placement of a peripherally inserted intravenous catheter, through the skin into a vein and when used according to the Instructions For Use (IFU) may reduce the risk of an accidental needle stick.

Substantial Equivalence

All predicate devices presented for comparison with the Safe-T-Peel® Safety Needle/Introducer are single patient, single use, stainless steel needle introducers with splittable sheaths, intended to facilitate the placement of Peripherally Inserted Catheters (PICs). Additionally the Safe-T-Peel® Safety Needle/Introducer contains a splittable plastic sheath identical to the one used in the TFX Medical Introducer Assembly (K993191).

The Safe-T-Peel® Safety Needle/Introducer is substantially equivalent to the previously cleared predicate device (K013304) with sharps injury prevention features because it has the same intended uses, similar principles of operation, similar technological characteristics and similar performance test results. The primary intended use is nearly identical to the primary intended use of Becton Dickinson's INTROSYTE Autoguard Shielded Introducer (K013304), TFX Corporation's TFX Medical Introducer Assembly (K993191), and TFX Corporation's TFX Medical Safety Needle with Introducer (K000665). The secondary intended use (protection against needle stick injury) is nearly identical to that of both theK013304 and K000665 predicate devices. The sharps injury prevention mechanism is essentially identical to the mechanism used in Becton Dickinson's INTROSYTE Autoguard Shielded Introducer (K013304).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2002

HDC Corporation
C/O Mr. Jonathan S. Kahan
Hogan & Hartson, LLP
Columbia Square
555 Thirteenth Street, NW
Washington. D.C. 20004-1109

Re: K022099
Trade/Device Name: Safe-T-Peel® Safety Needle Introducer
Regulation Number: 880.5200 and 870.1340
Regulation Name: Intravascular Catheter and Catheter Introducer
Regulatory Class: II
Product Code: FOZ and DYB
Dated: June 27, 2002
Received: June 27, 2002

Dear Mr. Kahan:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices). 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). 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

Indications for Use Statement

510(k) Number K

Device Name Safe-T-Peel Safety Needle Introducer

Indications for Use The Safety-T-Peel Safety Needle Introducer is used to facilitate placement of a peripherally inserted intravenous catheter, through the skin into a vein and when used according to the Instructions For Use (IFU) may reduce the risk of an accidental needle stick.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-counter Use _____
(Per 21 CFR 801.109)

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

510(k) Number: K022099