Univec, Incorporated
Randy Cohen
Regulatory Affairs Manager
22 Dubon Court
Farmingdale, New York 11735

November 1, 2024

Re: K020500
Trade/Device Name: Univec Bifurcated Sliding Sheath Syringe
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: SCL

Dear Randy Cohen:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 19, 2002. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code SCL.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact David Wolloscheck, OHT3: Office of GastroRenal, OB-Gyn, General Hospital and Urology Devices, 301-796-1480, David.Wolloscheck@fda.hhs.gov.

Sincerely,

David Wolloscheck -S

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and General Hospital Devices and Human Factors
OHT3: Office of GastroRenal, OB-Gyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2002

Mr. Randy Cohen
Regulatory Affairs Manager
Univec, Incorported
22 Dubon Court
Farmingdale, New York 11735

Re: K020500
Trade/Device Name: Univec Bifurcated Sliding Sheath Syringe
Regulation Number: None and 880.5860
Regulation Name: None and Piston Syringe
Regulatory Class: Unclassified and II
Product Code: LDH and MEG
Dated: February 13, 2002
Received: February 14, 2002

Dear Mr. Cohen:

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 Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020500

INDICATIONS FOR USE

The Univec Bifurcated Sliding Sheath Syringe is a safety version of a bifurcated needle attached to a syringe barrel with the Univec Sliding Sheath Syringe mechanism. The Univec Sliding Sheath mechanism is used to aid in the prevention of needle stick injuries. This device is used in the same manner as a standard Bifurcated Needle to deliver vaccine or allergen to the patient.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020500