



U.S. FOOD & DRUG
ADMINISTRATION

Precision Medical Products, Incorporated
Ronald D. Wolfe
Manager, Regulatory Affairs
12 Industrial Way
Denver, Pennsylvania 17517

November 1, 2024

Re: K031630

Trade/Device Name: Bifurcated Allergy Skin Testing Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: SCL

Dear Ronald D. Wolfe:

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 August 7, 2003. 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

AUG - 7 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ronald D. Wolfe
Manager, Regulatory Affairs
Precision Medical Products, Incorporated
12 Industrial Way
Denver, Pennsylvania 17517

Re: K031630
Trade/Device Name: Bifurcated Allergy Skin Testing Needle
Regulatory Class: Unclassified
Product Code: LDH
Dated: May 21, 2003
Received: May 27, 2003

Dear Mr. Wolfe:

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

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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. 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 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,

A handwritten signature in black ink that reads "Susan Runner". The signature is fluid and cursive, with the first name "Susan" and last name "Runner" clearly distinguishable.

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K031430

Device Name: Bifurcated Allergy Skin Testing Needle

Indications for Use:

The bifurcated allergy skin testing needle is indicated for in-vivo diagnostic skin testing using the puncture technique.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K031430