

K974327

510(K) Summary

Date: 12 November 1997

Trade Name: Removable wings

Common Name: Winged needle holder

Classification Name: Unknown

Device Description: The winged needle holder is fabricated from polyethylene.

Intended Use: This winged needle holder indicated for use in securing and positioning a hypodermic needle during the administration of a peribulbar nerve block.

Substantial Equivalence: This winged needle holder submitted device is substantially equivalent to the removable winged needle holder predicate device currently being sold in the United States by Becton Dickinson and Company, Franklin Lakes, New Jersey 07417. To the best of my knowledge, this predicate devices is being "legally" marketed.

Comparison to Predicate Device:

<u>Attribute</u>	<u>Predicate Device</u>	<u>Submitted Device</u>
Material of construction	Polyethylene	Polyethylene
Wing shape	Butterfly	Curved
Needle fit	Needle hub through holder	Needle hub through holder
Reuseability	Disposable	Disposable
Sterility	Sterile	Sterile

Submitter's Name	PHX Technologies Corporation
Submitter's Address:	1032 Shady Oaks Drive, No. 100, Denton, TX 76205
Submitter's Phone #:	(940) 387-5696
Submitter's FAX:	(940) 382-0577
Submitter's Contact Person:	James F. Chapel



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

James F. Chapel, Ph.D.
President
PHX Technologies Corporation
1032 Shady Oaks Drive, No.100
Denton, Texas 76205

JAN - 9 1998

Re: K974327
Trade Name: Winged Needle Holder
Regulatory Class: I
Product Code: FHQ
Dated: November 12, 1997
Received: November 18, 1997

Dear Dr. Chapel:

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.

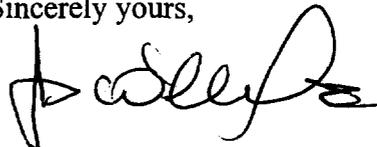
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 premarket 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.

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) 594-4595. 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,



fn Celia M. Witten, Ph.D., M.D.

Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K974327

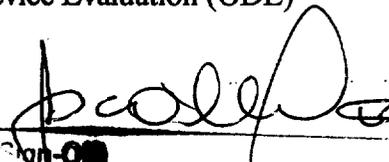
Device Name: WINGED NEEDLE HOLDER

Indications For Use:

Indications For Use: This winged needle holder is indicated for use in securing and positioning a hypodermic needle during the administration of a peribulbar nerve block.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



Special Representative
Number K974327

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)