4/6/99

Precision Dynamics Corporation
...products you can identify with®

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K990737

510k Summary

Precision Dynamics Corporation purchases the umbilical cord clamp (non-sterile) from Alpha Unlimited, Inc (refer to the 510k K894646) and then contracts the packaging and sterilization through ARMM, Inc. ARMM, Inc. packages the umbilical cord clamp in a plastic/film pouch and contract sterilizes the packaged product per Precision Dynamics Corporation specifications. Precision Dynamics Corporation upon receipt of the sterile finished released product from ARMM plans to distribute the Securline ® Cord Clamp.

The Securline ® Umbilical Cord Clamp is used to clamp over the umbilical cord of a newborn at delivery. The device is used to hold the cord secruely and prevent blood loss and seepage as the cord dries and shrinks after the birth.

Trade Name:	Securline ® Umbilical Cord Clamp #3500
Common Name :	Umbilical Cord Clamp
Classification Name:	Umbilical Clamp (per 21CFR section 884.4530(3)

Contact :	Kalyna Snylyk
Phone:	(818)897-1111 x 111
Fax:	(818)899-4045
Date:	March 3, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 6 1999

Ms. Kalyna Snylyk
Manager
Regulatory Affairs and Quality Assurance
Precision Dynamics Corporation
13880 Del Sur Street
San Fernando, CA 91340

Re: K990737
Securline® Umbilical Cord Clamp
Dated: March 4, 1999
Received: March 5, 1999
Regulatory Class: II
21 CFR 884.4530/Procode: 85 HFW

Dear Ms. Snylyk:

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 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). 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990737

Device Name: Securline Umbilical Cord Clamp #3500

Indications For Use:

The Securline Umbilical Cord Clamp is used to clamp over the umbilical cord of a Newborn at delivery. The device is used to hold the cord securely and prevent blodd loss and seepage as the cord dries and shrinks after the birth.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Krysmann
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990737