K994263

JAN 24 2000

510k Summary

Precision Dynamics Corporation purchases the packaged umbilical cord clamp clipper (non-sterile) from DeRoyal Industries. Precision Dynamics Corporation upon receipt of the non-sterile finished product from DeRoyal Industries plans to distribute this device as the Securline ® Umbilical Cord Clamp Clipper.

The Securline ® Umbilical Cord Clamp Clipper is used to cut the umbilical cord clamp off a newborn's umbilical cord.

Trade Name:	Securline ® Umbilical Cord Clamp Clipper #3540
Common Name :	Umbilical Cord Clamp Cutter
Classification Name:	Umbilical Clamp Cutter (per 21CFR section 884.4530(3)
Contact :	Kalyna Snylyk
Phone:	(818)897-1111 x 111
Fax:	(818)899-4045
Date:	Wednesday, December 15, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2000

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

Re: K994263
Securline® Umbilical Cord Clamp Clipper #3540
Dated: December 15, 1999
Received: December 17, 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): K994263

Device Name: Securline® Umbilical Cord Clamp Clipper

Indications For Use:

The Securline® Umbilical Cord Clamp Clipper is used to cut the umbilical cord clamp off a newborn's umbilical cord. The clipper jaws are placed over the "hinge" area of the umbilical cord clamp. Once appropriately located and engaged, pressure is applied to the clipper grips and the hinge is cut in half, removed, and disposed of properly.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices

510(K) Number K994263

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

(Optional Format 1-2-96)