



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 22 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Kalyna Snylyk  
Manager of Regulatory Affairs  
and Quality Assurance  
PRECISION DYNAMICS CORPORATION  
13880 Del Sur Street  
San Fernando, CA 91340

Re: K994353  
Securline® Disposable Fetal Monitoring  
Abdominal Straps, #3860 and #3565  
Dated: December 22, 1999  
Received: December 23, 1999  
Regulatory Class: II  
21 CFR §884.2720/Procode: 85 HFM

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) 594-4591. 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 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,

Daniel G. Schultz, M.D.  
Captain, USPHS  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure(s)

510(k) Number (if known): K994353

Device Name: Securline® Umbilical Disposable Fetal Monitoring Abdominal Straps

Indications For Use:

This product is to be used in a labor and delivery environment to secure a uterine contraction monitor to the mother's abdomen. The monitors are used to track contractions and baby's heartbeat rate. Two styles of straps are available. The first contains a buttonhole and the second contains Velcro slots on each end (watchlike). Therefore, one style of strap contains multiple "button holes" for adjustment and the second style of strap is made with Velcro hook and loop for adjustment and securing.

The straps are made of stretch fabric material and intended to be single-patient use. Both types of straps are packaged in pairs (one pink, one blue) shrink-wrapped and are available in quantities of fifty (50) pairs per box.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

David G. Seymour  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K994353