K020718

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

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# 510(k) Summary

JUN 0 3 2002

**Trade Name:** Securline ® Umbilical Cord Clamp #3505 and #3515

**Common Name :** Umbilical Cord Clamp

**Classification:** Umbilical Clamp (per 21CFR §884.4530(3)

**Predicate device:** Precision Dynamics Corporation identifies the following devices as a predicate:

- IM Inc. Umbilical Cord Clamp 510(k) 880753
- Hollister® Double Grip® Umbilical Cord Clamp 510(k) 781548
- Alpha Unlimited, Inc. Disposable Umbilical Cord Clamp 510(k) 894646

**Description of the device:** The Securline® Umbilical Cord Clamp is a single use, disposable, molded plastic device, unit packaged, (sterile) or bulk packaged (non-sterile).

**Intended use:** The Securline ® Umbilical Cord Clamp intended use is to clamp over the newborn infants umbilical cord at delivery and prevent blood loss as the cord dries and shrinks after the birth.

**Performance standards:**

No performance standards have been officially adopted by the FDA. The device tested by an independent laboratory for biocompatability (cytotoxicity and skin irritation) with favorable results. The device has been evaluated in comparison to predicate devices as to closing and gripping forces,

**Conclusion:** Precision Dynamics Corporation concludes that the function and use of the device is no different than that of the predicate devices.

**Submitter Information:** Precision Dynamics Corporation
Contact: Kalyna Snylyk
Telephone: (818) 897-1111

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 2002

Ms. Kalyna Snylyk
Manager of Regulatory Affairs
and Quality Assurance
Precision Dynamics Corporation
13880 Del Sur St.
SAN FERNANDO CA 91340

Re: K020718
Trade/Device Name: Securline® Umbilical Cord Clamp
#3505 (sterile), #3515 (non-sterile)
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized
manual instrument
Regulatory Class: II
Product Code: 85 HFW
Dated: January 30, 2002
Received: March 5, 2002

Dear Ms. Snylyk:

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 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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K020718

Device Name: Umbilical Cord Clamp #3505 (sterile) and #3515 (non-sterile)

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 blood 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 ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use____

(Optional Format 1-2-96)

David A. Ferguson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020718