AUG 27 1998

K972689

Attachment F

510(k) Summary
Compression Apparatus On Wheels (CAOW™) Hemostasis System

I. General Information

Device Generic Name:	Arterial puncture mechanical hemostasis system
Device Trade Name:	CAOW Hemostasis System
Applicant's Name and Address:	Anlam Corporation 10151 74th Street Edmonton, Alberta T6A 2X8 Canada
510(k) Number:	Compressar® (K925809; Instromedix) ClampEase (K863427; Freud Medical Products) Disco Pad and Quicklamp (K923085; TZ Medical)
Date of Judgement of Substantial Equivalence Sent to Applicant:	Compressar® (K925809) - 1992 ClampEase (K863427) - 1986 Disco Pad and Quicklamp (K923085) - 1992

II. Description of Conditions for Which the Product is Indicated

The CAOW Hemostasis System can be used to provide hemostasis for femoral arterial and venous punctures associated with an angiogram, angioplasty, coronary stent placement or other invasive cardiac or radiological procedures.

III. Device Description

The CAOW Hemostasis System consists of a pole-mounted C-clamp with movable upper and lower arms. A single-use, sterile acrylic plastic pad attached to the upper arm provides hemostasis by controlled compression of the arterial puncture site.

IV. Alternatives

Alternatives for the CAOW Hemostasis System are other commercially available hemostasis products, such as compression bandages, sutures, mechanical C-clamp pad compression systems, collagen plugs, etc.

V. Marketing History

The CAOW Hemostasis System is not in commercial distribution in the United States or elsewhere.

VI. Potential Adverse Effects

Potential adverse effects associated with the CAOW Hemostasis System are the same as those associated with other commercially available mechanical C-clamp pad compression systems.

VII. Summary of Studies

A sterilization validation, mechanical bench testing and a clinical study demonstrated the safety and proper performance of the CAOW Hemostasis System.

VIII. Conclusion

Information presented in this 510(k) Notification demonstrated the substantially equivalency of the CAOW Hemostasis System and provides reasonable assurance that the CAOW Hemostasis System will perform in a safe and effective manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 1998

Mr. Anthony Lam
Anlam Corporation
10536-101 Street
T5H 2R8
CANADA

Re: K972689
CAOW Hemostasis System
Regulatory Class: II (two)
Product Code: 74 DXC
Dated: August 11, 1998
Received: August 11, 1998

Dear Mr. Lam:

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) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment A

Indications for Use Statement

The indications for use recommended for the Compression Apparatus On Wheels (CAOW™) Hemostasis System are stated in the instruction manual (see Attachment B). This statement is repeated below:

> The CAOW Hemostasis System can be used to provide hemostasis for femoral arterial and venous punctures associated with an angiogram, angioplasty, coronary stent placement or other invasive cardiac or radiological procedures.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972689