



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 1999

Ms. Brenda Murphy
Regulatory Affairs Manager
SciCan
1440 Don Mills Road
Toronto, Ontario
CANADA M3B 3P9

Re: K983679
Trade Name: STATIM 5000 Cassette Autoclave
Regulatory Class: II
Product Code: FLE
Dated: December 4, 1998
Received: December 7, 1998

Dear Ms. Murphy:

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.

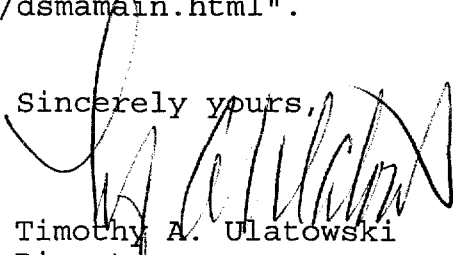
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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) 594-4692. 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" (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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE510 (K) Number: K983679Device Name: STATIM 5000 Cassette Autoclave with Extended Cassette

Indications for Use:

The STATIM 5000 Cassette Autoclave with Extended Cassette is a table-top steam sterilizer designed for the reprocessing of reusable instruments in a clinical setting.

The extended cassette will accommodate unwrapped stainless steel instruments of a longer and more complex construction to a weight of up to 1.5 kg. With the addition of the extended cassette, the STATIM 5000 unit will now accommodate longer length rigid scopes of up to 49 cm or 19".

The unit will process such instruments at a sterilization cycle of 132° C for 10 minutes.

NON PRESCRIPTION

Barney for Clin.
(Division Sign Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983679