K974180

510(K) SUMMARY
(as required by 807.92(c))

FEB 24 1998

Submitter of 510(k):

Regulatory & Marketing Services, Inc. (RMS)
3234 Ella Lane
New Port Richey, Florida 34655

Phone: 813-376-4154
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Contact Person: Ed Ransom

Date of Summary: November 3, 1997

Trade Name: Steri-Tamp

Classification Name: Seal, adhesive, accessory to IV container

Predicate Device: IVA Seal II

Device Description/ Comparison: The device is a seal used to cover and protect the septum surface of a previously opened vial, IV bottle or bag. The seal serves as a tamper resistant seal in that, once the seal; is removed, it can not be reattached to the septum.

	Pharmacy, Inc.	**U.S. Clinical Products**
Materials: Top Layer	Metalized Polyester	Metal
Bottom Layer	Polypropylene	Metal
Packaging:	Roll Stock on 3" core in a dispenser box	Same
Seals per roll	1000	Same
Dispenser Box	Sealed in a vented polypropylene bag	Same
Sterilization	ETO	Gamma Radiation
Reattach	Can not be reattached	Same
Coding	Multi-color	Same
Tampering	Tamper evident	Same
Removal	Pull Tab	Same

Intended Use: The product is a tamper evident, sterile seal used to cover opened pharmacy type drug containers. Such as vials, IV bottles, IV bags, etc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 1998

Mr. Ed Ransom
President
Pharmacy, Incorporated
C/O Regulatory & Marketing Services, Incorporated
3234 Ella Lane
New Port Richey, Florida 34655

Re: K974180
Trade Name: Steri-Tamp
Regulatory Class: II
Product Code: KPE
Dated: February 4, 1998
Received: February 6, 1998

Dear Mr. Ransom:

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 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 requirement, 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) 594-4618. 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/dsmamain.html".

Sincerely yours,

Susan Runner

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

Enclosure

510(k) Number (if known): _____

Device Name: STERI-TAMP

Indications For Use:

The product is a tamper evident, sterile seal used to cover opened pharmacy type drug containers. Such as vials, IV bottles, IV bags, etc.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K974180

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)