



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 1999

Mr. Matthew G. Sliva
Manager, Quality Assurance
North American Science Associates, Incorporated
2261 Tracy Road
Northwood, Ohio 43619-1397

Re: K983451
Trade Name: RSI® Process Challenge Device for Monitoring
Steam Sterilization Process
Regulatory Class: II
Product Code: JOJ
Dated: February 9, 1999
Received: February 11, 1999

Dear Mr. Sliva:

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.

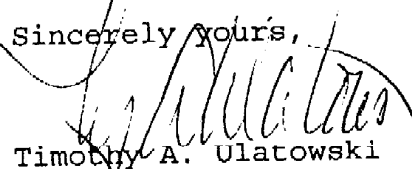
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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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" (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,



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

Enclosure



Corp. Hdqtrs: 226 Tracy Rd., Northwood, OH 43619-1397, 419.666.9455, Fax 419.666.2954
3400 Cobb International Blvd., Kennesaw, GA 30152-7601, 770.427.3101, Fax 770.426.5692
9 Morgan, Irvine, CA 92618-2078, 714.951.3110, Fax 714.951.3280
Affiliations: Taiwan • Germany • France

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: RSI® Process Challenge Device for Steam Sterilization (132°C/134°C Vacuum Assisted)

Indications for Use:

RSI Process Challenge Device is intended to be used in conjunction with RSI Rapid Indicators for Monitoring Steam Sterilization to monitor the effectiveness of wrapped loads at 132°C/134°C vacuum assisted steam sterilization cycles.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chun S. Lin
(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K 983451

Prescription Use 99~
(Per 21 CFR 801.109)

OR

Over-The-Counter Use 99~ **X**