

**510(k) Premarket Notification
Rowe Dual-Check Valve
COOK INCORPORATED**

11.1

Safety and Effectiveness Information

Submitted By: April Lavender, RAC
Vice President, Regulatory Affairs
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, In 47402
(812) 339-2235
September 11, 1998

Device: Trade Name: Rowe Dual-Check Valve
Proposed Classification Name: I.V. Connector

Predicate Device: Dual Check Valve Marketed by Burron
Distributed by COOK INCORPORATED

Device Description

The Rowe Dual-Check Valve is a disposable, inexpensive device that has been designed to infuse controlled volumes of fluid quickly. The Rowe Dual-Check Valve is a combination of two one-way flow valves joined by a "T" fitting. The arrangement allows a syringe to be placed on the medial female luer-lock port. The syringe is then used to draw fluid from the source and then infuse the fluid into the body.

The Rowe Dual-Check Valve uses one-way valves that are normally open. Therefore, when the system is placed in a normal intravenous system, gravity driven flow can pass through the device.

Indications for Use

The Rowe Dual-Check Valve is intended for use with IV cannula or extension tube sets for simultaneous or alternate administration of IV drugs and fluids. The check valve is used in conjunction with a standard Luer taper syringe.

Substantial Equivalence

The Rowe Dual-Check Valve is similar to another COOK INCORPORATED check valve which was found substantially equivalent under FDA DC #790062. The similar indications for use and technological characteristics of the Rowe Dual-Check Valve as compared to the predicate device supports a determination of substantial equivalency.

Test Data

The Rowe Dual-Check Valve was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests include:

- ◆ Pressure Test
- ◆ Flow Test
- ◆ Torque Test
- ◆ Biocompatibility

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as an I.V. connector.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 1999

Ms. April Lavender, RAC
Vice President, Regulatory Affairs
Cook Incorporated
925 South Curry Pike
P.O. Box 489
Bloomington, Indiana 47402

Re: K983217
Trade Name: Rowe Dual-Check Valve
Regulatory Class: II
Product Code: FPA
Dated: November 2, 1998
Received: November 4, 1998

Dear Ms. Lavender:

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

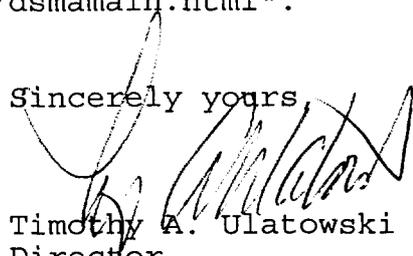
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

510(k) Premarket Notification
Rowe Dual-Check Valve
COOK INCORPORATED

510(k) Number (if known): K983217

Device Name: Rowe Dual-Check Valve

Indications for Use:

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off) B. Bolden
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983217