K974083

OHMEDA
THE BOC GROUP
Medical Devices Division

JAN 13 1998

Ohmeda Inc
The BOC Group Technical Center
100 Mountain Avenue
Murray Hill NJ 07974 2005
908 771 6100 Fax 908 771 6488

Attachment 8

510(k) Summary
Connecta® Plus 1 and Connecta® Plus 3 2-way and 3-way Stopcocks

Submitted by:
Ohmeda Inc., Medical Devices Division
100 Mountain Ave., Murray Hill, NJ 07974

October 27, 1997

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**
   Ms. Jing Zhang
   Phone: (908)771-6290 Fax: (908)771-1971

2. **Device Name and Classification:**

Trade Name:	Connecta® Plus 1 and Connecta® Plus 3 2-way and 3-way Stopcocks
Common Name:	Stopcocks
Classification Name:	IV Set Stopcock, IV Administration Set
Classification Panel:	General Hospital
CFR Section:	21 CFR §880.5440
Device Class:	Class II
Device Code:	80 FMG

3. **Substantial Equivalence:**
   The Connecta® Plus 1 and Plus 3 2-way and 3-way Stopcocks are substantially equivalent to our own Connecta® TH (through hole) 2-way and 3-way Infusion/Pressure Monitoring Stopcocks.

4. **Device Description:**
   The disposable Connecta® Plus 1 and Plus 3 2-way and 3-way Stopcocks consist of:
   - a smoke colored housing with three connectors: two female Luer fittings, and one male Luer fitting;
   - a color coded (white, blue, or red) rotating tap with eight (8) closed and open position indicators (snap on-off);

- a smoke colored collar nut assembled to the male Luer fitting in the housing. The rotating nut is used to secure the stopcock's connection with the product it is connected with.
- two white plugs attached to the two female Luer fittings in the housing;
- a white protection cap attached to the male Luer cone; and
- optional color-coded (blue or red) pegs used for line identification: blue for venous lines, and red for arterial lines.

5. **Intended Use of the Device:**
The Connecta® Plus 1 and Connecta® Plus 3 2-way and 3-way Stopcocks are intended to be used as control valves in I.V. therapy and hemodynamic pressure monitoring. They are added to IV cannula or extension tubing sets for simultaneous or alternate administration of IV drugs, fluids, and blood, or for blood sampling. They can also be used in areas in which solution flow requires control. Alternatively, they are used for hemodynamic monitoring via an arterial cannula and a central venous catheter.

6. **Summary of Technological Characteristics of the Device Compared to the Predicate Device:**
The new Plus 1 and Plus 3 stopcocks are similar in design and material as the predicate TH stopcocks. They all are used as control valves in I.V. therapy and hemodynamic monitoring. They all are for single patient use, irradiation sterilized, and pyrogen free.

In addition, the new Connecta® Plus 1 and Connecta® Plus 3 2-way and 3-way Stopcocks with the inner conic front in the A-port allows less air bubble entrapment and turbulence, and together with the larger lumen tap, also increases the flow rate, and improves priming condition and dynamic response. The position indicators added make it easier for the user to confirm if the stopcock is completely closed or open. The new grades of polycarbonate and polyethylene materials used improve the stopcocks resistance to cracking. The one-handle "OFF"-directing tap offered on Connecta® Plus 1 stopcock, instead of the three-handles on the existing predicate stopcocks is designed for customer preference only.

7. **Tests and Conclusion:**
Bench tests have been conducted to assess the effects of changes. All results are satisfactory.

Jing Zhang
Manager, Regulatory Affairs
Medical Devices Division
Ohmeda Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 1998

Ms. Jing Zhang
Manager, Regulatory Affairs
Ohmeda, Incorporated
Medical Devices Division
100 Mountain Avenue
Murray Hill, New Jersey 07974

Re: K974083
Trade Name: Connecta® Plus 1 and Connecta® Plus 3 2-Way and 3-Way Stopcocks
Regulatory Class: II
Product Code: FMG
Dated: October 27, 1997
Received: October 29, 1997

Dear Ms. Zhang:

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,

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

Enclosure

Attachment 1

Indications For Use

510(k) Number (if known): K974083

Device Name: Connecta® Plus 1 and Connecta® Plus 3 2-way and 3-way Stopcocks

Indications for Use:

Connecta® Plus 1 and Connecta® Plus 3 2-way and 3-way Stopcocks are control valves for use in I.V. therapy and hemodynamic pressure monitoring. They are added to IV cannula or extension tubing sets for simultaneous or alternate administration of IV drugs, fluids, and blood, or for blood sampling. They can also be used in areas in which solution flow requires control. Alternatively, they are used for hemodynamic monitoring via an arterial cannula and a central venous catheter.

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

Patricia Cusante

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974083

Prescription Use ✓ OR Over-The-Counter Use _____
(per 21 CFR 801.109)