

K973364
p. 1/2

MAR 17 1998

510(k) Summary

1. Trade/propriety name:

Urias and Pharma Plast brand names will be used but products may also be marketed without brand names especially in case of OEM products or in some cases with private labels.

2. Common/usual name: 4L Drainage bag

3. Classification name: Gasenterology and urology

4. Establishment Registration number: 8021523

5. Manufacturing/sterilization facility address:

Maersk Medical A/S
Drainage Bags
Haarlev Mark 2
DK - 4652 Haarlev, Denmark.

6. Substantial equivalence:

The products included in this notification is equivalent to the components described in K843480.

7. Device Description.

The general description, operation, construction and use of the Maersk Medical 4L drainage bag has not changed as a result of the modifications.

The 4L drainage bag contains basically the same features as the device described in K843480 and the manufacturing process is identical. However the 4L drainage bags will hold 4000 ml. compared to 2000 ml. for the device described in K843480. On a few points features has been added to the 4L drainage bag, but they are all added to improve patient and healthcare personnel comfort.

8. Intended use.

The basics of the intended use has not changed. The Maersk Medical 4L drainage bag continue to be intended for collection of fluid which is on its way away from the body. The 4L drainage bag can be used in different treatment procedures within areas as urology and dialysis, but in any case the intended use is the same. The 4L drainage bag will not come into contact with neither skin or drugs and therefore no biocompatibility



K973364
p. 2/2

test has been carried out.

9. Technological Characteristics.

The technological characteristics of the device has not been affected by these modifications.

10. Performance Data.

The performance data showed that the product has lives up to high quality performance demands that fully shows that the 4L drainage bag is substantially equivalent to the unmodified device.

11. Conclusion

Based on the equivalency in all the mentioned areas including functional and quality testing, Maersk Medical has determined that the 4L drainage bag are substantially equivalent to the devices currently marketed in the United States.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Joergen M. Nielsen
Product Manager
Maersk Medical A/S
Harlev Mark 2
4652 Harlev, DENMARK

Re: K973364
Arias and Pharma Plast Drainage Bag
Dated: February 13, 1998
Received: February 17, 1998
Regulatory Class: II
21 CFR 876.5250/Procode: 78 KNX
21 CFR 876.5630/Procode: 78 FKX

MAR 17 1998

Dear Mr. Nielson:

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 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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973361

Device Name: 4L Drainage Bag

Indications For Use:

The device label will state the following:

- A: "Peritoneal Dialysis Drainage bag"
- B: "Collection bag for urine"

Maest Medical A/S
 - Jørgen Ham 18/12-97
[Signature]

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Robert D. Rathling
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K973364