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Summary of Safety and Effectiveness

APR 14 1997

Denver® Pleural Effusion Shunt with External Pump Chamber

SUBMITTER INFORMATION

Denver Biomaterials, Inc.
6851 Highway 73
Evergreen, Colorado 80439 USA

Lynne Leonard
Director, Regulatory Affairs/Quality Assurance

DEVICE COMMON NAME

Pleuro-peritoneal Shunt

DEVICE CLASSIFICATION NAME

78

21 CFR 876.5955 (Peritoneo-venous Shunt, #79KPM).

IDENTIFICATION OF SUBSTANTIALLY EQUIVALENT DEVICE(S)

The Denver® Pleural Effusion Shunt with External Pump Chamber, Catalog No. 42-9005, is substantially equivalent in intended use to the Denver® Pleural Effusion Shunt, Catalog No. 42-9000. Both devices have the same intended use; both are single-use, non-pyrogenic, sterile, pleuro-peritoneal shunts. With the exception of the polyester cuffs and longer catheters on the Denver® Pleural Effusion Shunt with External Pump Chamber, the two devices are identical in configuration, materials and manufacturing processes.

B. The Denver® Pleural Effusion Shunt with External Pump Chamber, Catalog No. 42-9005 is also substantially equivalent to the Cook, Inc. Pneumothorax Set in that both have a radiopaque catheter designed to be placed with one end in the pleural space and the other end external to the body.

C. The Denver® Pleural Effusion Shunt with External Pump Chamber, Catalog No. 42-9005 is also substantially equivalent to the Quinton Tenckhoff Peritoneal Dialysis Catheter in that both have a radiopaque catheter designed to be placed with one end in the peritoneal cavity and the other end external to the body.

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DEVICE DESCRIPTION:

The Denver® Pleural Effusion Shunt with External Pump Chamber is a sterile, non-pyrogenic device, for single use only. It is not to be resterilized. The one-piece device consists of a 15.5 Fr. fenestrated pleural catheter and a 15.5 Fr. fenestrated peritoneal catheter, separated by a flexible pump chamber containing two one-way valves. The flexible pump chamber is designed to be manually pumped by the patient or caregiver to transfer pleural fluid from the pleural cavity into the peritoneal cavity. The valves in the pump chamber permit flow in one direction only. The second valve in the pump chamber serves as a check valve for the first, helping to prevent reflux of fluid into the peritoneal catheter when the pump chamber is pumped.

Each catheter has a polyester cuff located between the pump chamber and the catheter's fenestrations. When the device is placed in a patient, the pleural and peritoneal catheters are implanted into the pleural and peritoneal cavities, respectively, with the cuffs subcutaneous to permit tissue ingrowth into the cuff. The pump chamber remains outside the patient's body. The entire device is made of silicone rubber, with the exception of the cuffs, which are polyester. Both the pleural and peritoneal catheters contain an integral barium sulfate stripe to permit visualization by x-ray or fluoroscopy.

INTENDED USE

The Denver® Pleural Effusion Shunt with External Pump Chamber, Catalog No. 42-9005 is indicated for use in transferring pleural fluid, resulting from chylothorax or intractable pleural effusion, from the pleural cavity to the peritoneal cavity. The device is intended to be used in adult, pediatric, and neonatal patients.

SCIENTIFIC LITERATURE

Published studies indicate that pleuro-peritoneal shunting is a safe and effective procedure.