

SAFETY AND EFFECTIVENESS SUMMARY

PROPRIETARY NAME

JUL 24 1996

Pruitt Biliary Catheter

COMMON/USUAL NAME

Biliary Catheter

CLASSIFICATION: 21 CFR 876.5010

DEVICE DESCRIPTION

The Pruitt biliary catheter is a radiopaque multi lumen, balloon catheter. The ancillary lumen(s) are for injection and/or irrigation; another lumen inflates the balloon. All materials have been used by Ideas for Medicine, Inc. in cardiovascular catheters and/or laparoscopic instruments with no report of adverse events. All materials have been subject to testing per the Biocompatibility testing.

INTENDED USE

The Pruitt Biliary Catheters are intended for use in the removal of stones, ductal debris and the exploration of the biliary tube.

SUBSTANTIAL EQUIVALENCE

The materials used to manufacture these devices are identical to the materials used to manufacture the Pruitt Irrigation-Embolectomy catheters, Pruitt Irrigation Occlusion Catheters, Robiscek Angiography-Embolectomy Catheters, the Reddick Cystic Duct Catheters and the Grice Laparoscopic Sump manufactured by Ideas for Medicine, Inc. The intended use of this device is substantially equivalent in function and intended use to the Fogarty Biliary Balloon Probe, the Edslab Irrigation Catheter, the Ideas for Medicine Trilumen Intravascular Catheter for Gu Use and the Bard Stone Removal Balloon Catheters. These are used to remove ductal debris, stones and exploration of the biliary tree. Irrigation capabilities can facilitate lubrication, flushing and cholangiography.