

K955126

LMI BILIARY CATHETER

510K NOTIFICATION
PAGE 1 OF 18LUCAS MEDICAL, INC.
1751 S. DOUGLASS ROAD, ANAHEIM CA 92806

MAY 10 1996

510K SUMMARY

PURPOSE: Pursuant to the Federal Food, Drug, and Cosmetic Act, as amended May 28, 1976, Section 510(k), please consider the attached document as Lucas Medical, Inc.'s notification of intent to introduce the LMI Biliary Catheter for commercial distribution. The common names for the device are silicone Biliary catheter and Biliary catheter.

BACKGROUND: This 510K submission should be considered as a new application. On March 17, 1995, a 510K was submitted for this product and was issued a reference number of K951310. Additional information was requested on April 4, 1995. In accumulating the data to answer the questions raised, the extension time allotted by the FDA expired. This new 510K submission addresses those earlier questions.

MANUFACTURING & STERILIZATION SITES: The manufacturing and packaging facility is: Lucas Medical Inc., 1751 S. Douglass Road, Anaheim CA 92806. The establishment registration number is: 2029386. Sterilization will be performed by Griffith MicroScience (Establishment Registration Number: 2011171) 4900 S. Gilford, Los Angeles CA 90058.

DESCRIPTION: The catheter consists of a single lumen stainless steel wire reinforced silicone tube that is end formed to create a rounded leading nose. A silicone balloon is bonded to the distal end of the catheter at the end form. The proximal end of the catheter consists of a female luer connector and a strain relief that are bonded to the silicone shaft. The "DEVICE" is packaged in an EtO breathable tray for protection and then sealed in an EtO breathable pouch. It is EtO sterilized and non-pyrogenic. The "DEVICE" is for Single Use Only and is used only By or On the Order of a Physician.

CLASSIFICATION: The "DEVICE" is a Class II Medical device and has a classification number of 78FGE and is reviewed by the Gastroenterology and Urology Review Panel.

INTENDED USE: The device is intended for intra-operative short term use in the biliary tree to aid in the removal of ductal stones and debris.

PRINCIPLE OF OPERATION: Biliary catheters are generally used in surgical procedures for removal of gall stones in the biliary duct. Access to the bile duct is made through the choledochotomy. The catheter is inserted into the bile duct and advanced beyond the region where stones and debris are present. The balloon is carefully inflated to occlude the bile duct while not overly distending it, and then gently withdrawn to push the stones and debris out of the bile duct at the access point. Once the bile duct has been cleared, the remaining choledochotomy is surgically closed.

SUBSTANTIAL EQUIVALENCE: The "DEVICE" is substantially equivalent to the ABI Cathlab Silicone Biliary Catheter which was approved under 510(k) notification K910917. The design parameters and intended use of the "DEVICE" are the same as the substantially equivalent catheter. The "DEVICE" utilizes the same materials of construction and packaging as the substantially equivalent catheter.