

OCT 25 1996

510 (k) SUMMARY

K 96 2925
P1072

OLYMPUS B5/B7 BALLOON Catheter

Device Name: Olympus B5/B7 Balloon Catheter

Common/Usual Name: Balloon Catheter

Classification Name: Endoscope and Accessories

Predicate Devices: Olympus B5/B7 Biliary Balloon Catheter (K904669)

**Submitted By:
(Contact Person)** Mr. Barry Sands
Olympus America Inc.
Endoscope Division
Two Corporate Center Drive
Melville, New York 11747-3157
(516) 844-5474

Summary Preparation Date: July 17, 1996

Statement of Intended Use

B5-2Q/B5-2LA Balloon Catheters (Color of Branch - Blue)

The B5-2Q/B5-2LA Balloon Catheters are designed to be used as an accessory to Olympus endoscopes with a minimum channel size of 2.0 mm.

B7-2Q/B7-2LA Balloon Catheters (Color of Branch - Yellow)

The B7-2Q/B7-2LA Balloon Catheters are designed to be used as an accessory to Olympus endoscopes with a minimum channel size of 2.8 mm.

Indications for Use:

B5-2Q/B5-2LA and B7-2Q/B7-2LA Balloon Catheters (Four Models)

The B5-2Q/B5-2LA and B7-2Q/B7-2LA Balloon Catheters are to be used for biliary or pancreatic stone removal and dye injection associated with ERCP.

Device Description

The balloon catheter is designed to be used as an accessory to Olympus endoscopes. It is introduced to the desired anatomical site through an instrument channel of an endoscope.

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The Balloon Catheter is constructed of an inflatable balloon, catheter, branch, irrigation port, air feed cap, and stopcock. The B5 series Catheters are 5 French in diameter and designed to be used with minimum 2.0 mm channel endoscopes, while the B7 series balloons are 7 French in diameter and should be used with minimum 2.8 mm channel size endoscopes. They are identified by a color code. For example, B5 series have been identified with the blue color branch and B7 series catheters have the yellow color branch. They are available in two different lengths for the specific needs, which the final letter designates as follow:

<u>Final Letter</u>	<u>Length</u>
Q	1950 mm
LA	3500 mm

General Safety

In conclusion, when compared with the predicate biliary balloon (K904669), the subject Olympus B5/B7 Series Balloon Catheters do not incorporate any significant change in the design, specifications, intended use, or method of operation that could affect the safety or efficacy of the subject devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 25 1996

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Barry E. Sands
Regulatory Affairs Manager
Olympus America, Inc.
Two Corporate Center Drive
Melville, New York 11747-3157

Re: K962925
Olympus B-5/B-7 Series Balloon Catheter
Dated: July 23, 1996
Received: July 29, 1996
Regulatory Class: II
21 CFR 876.1500/Product Code: 78 FGE

Dear Mr. Sands:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4616. 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 at (301) 443-6597.

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Not assigned yet.

Device Name: Olympus B5/B7 Series Balloon Catheters

Indications for Use:

B5-2Q/B5-2LA and B7-2Q/B7-2LA Balloon Catheters (Four Models)

The B5-2Q/B5-2LA and B7-2Q/B7-2LA Balloon Catheters are to be used for biliary or pancreatic stone removal and dye injection associated with ERCP.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert A. Rathgib
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

Prescription Use ✓
(per 21CFR 801.109)

510(k) Number OR K962925 Over-the Counter Use _____
(Optional Format 1-2-96)

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