

K962901

**AUG 20 1996** 510 (k) SUMMARY

**OLYMPUS B5-2C/B7-2C BALLOON CATHETER**

**Device Name:** Olympus B5-2C/B7-2C Balloon Catheters

**Common/Usual Name:** Balloon Catheter

**Classification Name:** Bronchoscope and Accessories

**Predicate Devices:** Olympus B5-2C/B7-2C Biliary Balloon Catheter (K904669)

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**Statement of Intended Use**

**B5-2C Balloon Catheter** (Color of Branch - Blue)

The B5-2C Balloon Catheter is designed to be used as an accessory to Olympus endoscopes with the minimum channel size of 2.0 mm.

**B7-2C Balloon Catheter** (Color of Branch - Yellow)

The B7-2C Balloon Catheter is designed to be used as an accessory to Olympus endoscopes with the minimum channel size of 2.8 mm.

**Indications for Use:**

**B5-2C/B7-2C      Balloon Catheters      (Two Models)**

Olympus B5-2C/B7-2C Balloon Catheters are to be used for selective endoscopic bronchography, medicine injection to bronchi, saline injection associated with bronchoalveolar lavage, foreign body removal from bronchi, and bronchial hemostasis (tamponade).

**Device Description**

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

The subject device is constructed of the inflatable balloon, catheter, bifucation, irrigation port, air feed cap, and stopcock. The B5 series balloon catheter is 5 French in diameter and designed to be used with minimum 2.0 mm channel endoscopes, while the B7 series balloon catheter is 7 French in diameter and should be used with minimum 2.8 mm channel size endoscopes. They are identified them 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. The length of both catheters is 1050 mm.

### **General Safety**

In conclusion, when compared with the predicate biliary balloon (K904669), the subject Olympus B5-2C/B7-2C Balloon Catheter does not incorporate any significant change in the design, specifications, or method of operation that could affect the safety or efficacy of the subject devices.