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### 510(k) SUMMARY

#### A. Submitter Information

Submitter's Name: Navarre Biomedical Ltd.

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Submission  
Preparation Date: November 2, 1995

#### B. Device Information

Trade Name: Navarre Percutaneous Biliary Drainage Catheter

Common Name: Biliary Drainage Catheter

Classification  
Name: Biliary Catheter (21 CFR 876.5010)

Predicate Device: This 510(k) summary identifies the Navarre Locking Pigtail Universal Drainage Catheter and the Navarre Universal Drainage Catheter, as substantially equivalent to the proposed Navarre Percutaneous Biliary Drainage Catheter. The Biliary Catheter is also substantially equivalent to the predicate Cook Ultrathane™ Biliary Drainage Catheter and the Mediatech VTCB Biliary System™ designs.

Device Description: The proposed Percutaneous Biliary Drainage Catheter is identical to the predicate Navarre Locking Pigtail Universal Drainage Catheter in that they have identical

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tip-locking mechanisms. They differ only in the length of the distal ported section, catheter length, addition of a flexible cannula, number of drain holes, and the addition of a biliary septum to inject fluids into the bile duct.

**Intended Use:** The intended use of the Percutaneous Biliary Drainage Catheter is to treat patients with obstructive jaundice, sepsis, and hepatic decompensation and pre-operative decompression.

### C. Comparison of Required Technological Characteristics

The Percutaneous Biliary Drainage Catheter is substantially equivalent to the commercially-available Locking Pigtail Universal Drainage, Navarre Universal Drainage, Cook Ultrathane™ Biliary Drainage Catheter, and the Medi-tech VTCB Biliary System™. The Biliary Catheter differs technologically from Navarre predicates only in that it has a modified metallic reinforcement, a more flexible cannula, and a biliary septum. Testing showed that the Percutaneous Biliary Drainage Catheter does not raise any new questions of safety and effectiveness.

### Comparison of Required Characteristics

<b>Characteristics</b>	<b>Proposed Navarre Percutaneous Biliary Drainage Catheter</b>	<b>Predicate Navarre hydrophilic Universal Drainage Catheter</b>	<b>Predicate Navarre Locking Pigtail Universal Drainage Catheter</b>	<b>Predicate Cook Ultrathane Biliary Catheter</b>	<b>Predicate Medi-tech VTCB Biliary System</b>
a. Product Labeling	Substantially equivalent	Substantially equivalent	Substantially equivalent	Substantially equivalent	Substantially equivalent
b. Intended Use	Obstructive jaundice, sepsis, hepatic decompensation and pre-operative decompression	Nephrostomy, abscess and general drainage	Abscess, cyst, and general purpose drainage	Identical to proposed catheter	Identical to proposed catheter
c. Physical Characteristics	Substantially equivalent	Substantially equivalent	Substantially equivalent	Substantially equivalent	Substantially equivalent
d. Anatomical Sites	Bile duct and duodenum	Kidney and general drainage sites	Abscessed sites	Identical to proposed catheter	Identical to proposed catheter
e. Target Population	Patients with obstructive jaundice, sepsis and hepatic decompensation and pre-operative decompression	Patients requiring kidney, abscess, or other general drainage applications	Patients with abscess and general drainage needs	Identical to proposed catheter	Identical to proposed catheter
f. Performance Testing	Substantially equivalent	Substantially equivalent	Substantially equivalent	Substantially equivalent	Substantially equivalent
g. Safety Characteristics	Identical	Identical	Identical	Substantially equivalent	Substantially equivalent

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#### D. Summary of Nonclinical Tests

Laboratory tests for cytotoxicity showed that the Percutaneous Biliary Drainage Catheter is non-cytotoxic. Qualification tests demonstrate that the physical characteristics of the catheter are equivalent to predicate devices. In conclusion, the laboratory results show that the Percutaneous Biliary Drainage Catheter design does not raise any new questions of safety and efficacy and that the Biliary Catheter is substantially equivalent to the current Locking Pigtail Universal Drainage, Navarre Universal Drainage, Cook Ultrathane™ Biliary Drainage Catheter, and the Medi-tech VTCB Biliary System.™