

SEP - 5 2006

**510(k) Summary**

**Submitter Information:**

Aus Systems Pty Ltd  
3 Charles Street  
Allenby Gardens, South Australia 5009  
Australia

**Contact:**

Ian P. Gordon

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**Date Prepared:**

July 26, 2006

**Product Name & Classification:**

RB12 Suction Rectal Biopsy System  
Class II, per 876.1075  
Panel: Gastroenterology/Urology  
Product Code: FCK

**Description:**

The RB12 consists of a gamma sterilized single use polystyrene closed end cylinder shaped capsule with a small hole at the closed end which contains a stainless steel cutting blade and a polyethylene seal. The capsule connects to a re-useable handpiece (HP1000) via a quick twist and lock system and suits both left and right handed operators. The HP1000 has an inner piston which automatically locates in the internal seal when the capsule is connected. This creates an airtight loop to the attached syringe via the suction tube/syringe adaptor. The inner piston is pushed forward when the thumb trigger is activated pushing the blade forward past the capsule hole cutting the specimen.

The RB12 design uses a combination of a re-useable handpiece and a disposable (single use) capsule. The capsule is supplied to the end users in a sterile state completely assembled with an internal blade and seal.

A syringe is connected to the rear end of the internal trigger tube via a piece of suction tube and a syringe/tube adaptor (supplied sterile with capsules). The disposable capsule is placed onto the outer tubing that is housed within the handle. While placing the capsule the internal trigger tube automatically locates and passes through the seal. When capsule is placed onto the handpiece it creates an air loop from the syringe to the front section of the capsule. The capsule is placed against the mucosal wall of the rectum of the patient covering the capsule port. When the syringe is withdrawn this causes negative pressure in the capsule sucking the mucosal and sub mucosal into the capsule. The thumb trigger is pushed forward which pushes the blade forward cutting the tissue that has been sucked into the port. The front of the capsule remains airtight as the trigger/inner tube slides through the internal seal.

### Indications for Use:

The RB12 Suction Rectal Biopsy System is intended to provide biopsy specimens of the rectal mucosa and submucosa suitable for pathological examination for the diagnosis of Hirschsprung's disease.

### Substantial Equivalence:

This device is substantially equivalent to the Model SBT-100 Rectal Suction Biopsy Tool, marketed under K902097 by Medical Measurements, Inc.

Description	Predicate Device SBT-100 K902097	Proposed Device Aus systems - RB12
Handpiece for instrument placement	✓	✓
Cylindrical tube housed within handpiece	✓	✓
Cylindrical tube distal end connects to closed end capsule	✓	✓
Capsule has side port to allow specimen to be sucked into capsule under negative pressure	✓	✓
Aspiration connection to cylindrical tube	✓	✓
Internal blade to cut tissue whilst under negative pressure	✓	✓
Pressure seal mechanism	✓	✓
Trigger to activate blade	✓	✓
Insertion depth measurement indicators	✓	✓
Intended use	Rectal biopsy specimen collection	Rectal biopsy specimen collection
Blade size	Unknown	5mm x 7mm
Insertion depth	Various	Various 1-5 cm
Sample notch size	2.5mm	2.4 - 2.7mm
Number of samples	multiple	1 per capsule
Mode of action	Suction	Suction

Target population	Trained physician	Trained physician
Visualization techniques	Insertion depth markers on outer surface	Insertion depth markers on outer surface
Method of placement	Port side Posteriorly within the rectum	Port side Posteriorly within the rectum 1-5cm
Reusability	All parts reusable	Reusable handpiece, disposable (single use) capsule

**Voluntary Standards Applied:**

ISO 13485	Quality Systems
ISO 10993-1	Biological Evaluation of Medical devices Part 1: Evaluation and Testing
ISO 11737	Sterilization of Health Care Products – Requirements for validation and routine control -Radiation Sterilization
AAMI-TIR27	Sterilization of Health Care Products - Radiation Sterilization – Substantiation of 25kGy as a Sterilization Dose – Method VD
ISO 11607	Packaging for terminally Sterilized Medical Devices
ISO17664	Sterilization of Medical Devices Information to be provided by the manufacturer for the processing of resterilizable medical devices.
ISO 7153-1	Surgical Instruments – Metallic Materials
EN 1441	Medical Device – Risk Analysis
EN 1041	Medical Devices – Information supplied by Manufacturer
EN 980	Graphical Symbols for Use in the Labeling of Medical Devices

**Performance Data:**

Bench testing was performed including a seal test, a chisel blade test, and an assembled capsule test.

**Critical Evaluation:**

A critical evaluation of the RBI-2 device has been performed by pediatric surgeon J K Freeman, MBBS FRACS, whose credentials include the following:

- Senior Visiting Surgeon, Women’s and Children’s Hospital, Adelaide, South Australia
- Senior Lecturer in Pediatric Surgery, University of Adelaide
- Chief of Pediatric Surgery, Flinders Medical Center, Adelaide, South Australia
- Senior Lecturer in Pediatric Surgery, Flinders University



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

Aus Systems PTY Ltd.  
c/o Mr. Ian P. Gordon  
Senior Vice President  
Emergo Group, Inc.  
2454 McMullen Booth Road  
Suite 427  
CLEARWATER FL 33759

SEP - 5 2006

Re: K062159  
Trade/Device Name: RB12 Suction Rectal Biopsy System  
Regulation Number: 21 CFR §876.1075  
Regulation Name: Gastroenterology-urology biopsy instrument  
Regulatory Class: II  
Product Code: FCK  
Dated: July 26, 2006  
Received: July 31, 2006

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



*Protecting and Promoting Public Health*

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) # (if known): K062159

Device Name: RB12 Suction Rectal Biopsy System

**Indications for Use:**

The RB12 Suction Rectal Biopsy System is intended to provide biopsy specimens of the rectal mucosa and submucosa suitable for pathological examination for the diagnosis of Hirschsprung's disease.

Prescription Use   x    
(21 CFR 801 Subpart D)

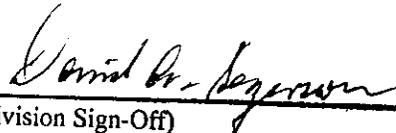
~~AND/OR~~

Over-the-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K062159