

**Appendix A: 510(k) SUMMARY**

**1. Date of Summary**

March 2, 2009

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**2. 510(k) Applicant**

Broncus Technologies, Inc.  
1400 N. Shoreline Blvd., Bldg. A, Suite 8  
Mountain View, California 94043  
Phone: (650) 428-1600  
FAX: (650) 428-1542

Contact Person: Nancy Isaac  
Phone: (650) 428-1600 ext. 305  
Fax: (650) 428-1542  
e-mail: nisaac@bronus.com

**3. Device Overview**

Trade Name: Yield™ Mini Doppler System  
Common Name: Doppler Probe and Processing Unit  
Classification Name: Radiology Device  
21 CFR 892.1550  
Product Code IYN

**4. Predicate Device**

The predicate devices identified for the Yield Mini Doppler Probe are as follows:

Trade Name	510(k) Submitter	510(k) Number
Exhale Doppler System	Broncus Technologies, Inc	K010649, cleared to market on March 20, 2001
P.D. Access Percutaneous Doppler Vascular Device and P.D. Access Dual Frequency Monitor	Cardiovascular Dynamics, Inc	K973713, cleared to market on January 23, 1998

**5. Device Description**

This premarket notification covers Broncus' Yield Mini Doppler System, which comprises the Yield Mini Doppler Probe and Broncus Monitor. The Mini Doppler System will enable

**Broncus Technologies, Inc.**

the bronchoscopist to identify vessel-free areas prior to performing transbronchial procedures such as needle aspiration or biopsy.

#### **6. Intended Use**

The Yield Tissue Mini Doppler Probe with Broncus Monitor is intended for use through a bronchoscope to detect blood flow behind the airway wall in the tracheobronchial tree.

#### **7. Comparison to Predicate Device**

The Yield Mini Doppler System is substantially equivalent to the predicates. The Mini Doppler System has the same intended use, methods of introduction, method of operation and design features. Furthermore, all materials were tested for biocompatibility per ISO10993, *Biological Evaluation of Medical Devices*.

#### **8. Performance Data**

Performance testing of the Yield Mini Doppler System included mechanical, thermal and electrical safety testing. These tests demonstrate that all items tested were within specification tolerances. There were no failures during the testing.

#### **9. Safety and Effectiveness**

The Yield Mini Doppler Probe and Broncus Monitor labeling contain instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device. The biocompatibility assessment was performed in accordance with ISO10993, *Biological Evaluation of Medical Devices*. In addition, the device will be sterilized using e-beam sterilization.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Broncus Technologies, Inc.  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

APR - 3 2009

Re: K090743  
Trade/Device Name: Yield™ Mini Doppler System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN and ITX  
Dated: March 19, 2009  
Received: March 20, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket 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 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Yield™ Mini Doppler System, as described in your premarket notification:

Transducer Model Number

Yield Mini Doppler Probe 11781

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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.

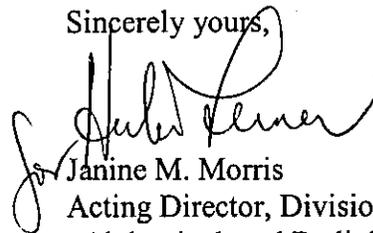
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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 market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. 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>

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure(s)

**Indications for Use Statement**

510(k) Number: K 090743

Device Name: Yield™ Mini Doppler System

Indications for Use: The Yield Mini Doppler Probe with Broncus® Monitor is intended for use through a bronchoscope to detect blood flow behind airway walls in the tracheobronchial tree.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

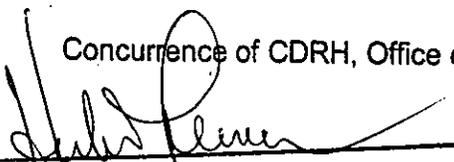
AND/OR

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number \_\_\_\_\_

K 090743

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**Ultrasound Indications for Use Form**

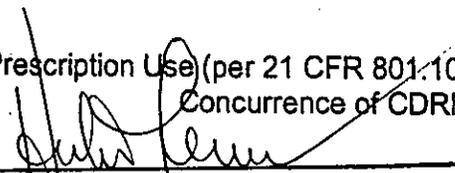
System: Yield Mini Doppler System  
 Transducer: Yield Mini Doppler Probe 11781  
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
Intravascular								
Other (Specify)					N <sup>a</sup>			
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Other (Specify)								
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N<sup>a</sup>: Intraluminal ultrasound for the tracheobronchial tree.  
 N = new indication; P = previously cleared by FDA; E = added under this appendix  
 \*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging Doppler, and Color Velocity Imaging

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Prescription Use (per 21 CFR 801.109)  
 Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal and Radiological Devices  
 510(k) Number K090743