

k971702

*Safety and Effectiveness Summary  
INT13 Biopsy Accessories  
Biosound Esaote*

## **Safety and Effectiveness Summary**

The following safety and effectiveness summary has been prepared pursuant to requirements for 510(k) summaries specified in 21 CFR 807.92.(a)

807.92(a)(1)

JUL - 9 1997

### **Submitter Information**

Gerald A. Richardson, Official Correspondent  
8000 Castleway Drive  
Indianapolis, Indiana 46250  
Phone: (317) 849-1793  
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Contact Person: Gerald A. Richardson

Date: April 27, 1997

807.92(a)(2)

Trade Name: Biopsy attachment and handle

Common Name: Punch, biopsy

Classification Name(s): Punch, biopsy 876.1075

807.92(a)(3)

Predicate Device(s)

<b>Company</b>	<b>Article</b>	<b>510 (k)</b>
Esaote	ABS1, ABS2, ABS3,	K912088
Diasonics	New Image	K831317

Additional Substantial Equivalence information is provided in the attached Substantial Equivalence Comparison Table.

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807.92(a)(4)

Device Description

The Biopsy accessory attachment and handle, function with the ESAOTE Ultrasound Transducer previously cleared via K953819, connected with the AU4 Ultrasound system cleared via K944485/S3.

The biopsy accessories consist of a metal and plastic bracket and needle guides that attach to the ultrasound transducer. The AU4 system software provides for the guidance of the biopsy needle through the biopsy accessory needle guide.

Information describing the device specifications is provided in the following substantial equivalence comparison table in Section 807.92(a)(6) Substantial Equivalence.

The Biopsy needles are not provided as part of the accessory.



Specifications

<b>ITEM</b>	<b>CHARACTERISTICS</b>	<b>DIMENSION</b>
Probe Handle	Polyurethane Resin	
Biopsy Attachment	Stainless Steel	
Needle Guide	Stainless Steel	14-18-20-21-22

## Materials

The Handle is one part of the Biopsy accessories. This component has been designed with polyurethane resin 6090 black: Resin Polyuretana nera.

Following ISO 10993 or EN 30993 this material is classified as External Communicating Device Tissue Bone Dentin Communicating : **Class A-Limited** ( less or equal to 24 hours).

The Tests requested are:

- CYTOTOXICITY
- SENSITISATION
- IRRITATION

These tests were performed by **Biolab** the Italian Laboratory located in Milan at Vimodrone Via Buozi 2 tel +39-2-250715-1, in accordance ISO 10993.

## Sterilization

*FOLLOW THE INSTRUCTIONS PROVIDED BY THE MANUFACTURER OF THE CIDEX SOLUTION TO PERFORM PROPER STERILIZATION.*

Recommended sterilizing solution.

Cidex Activated Dialdehyde Solution  
Johnson & Johnson.  
(P.O. Box 90130 Arlington, Texas 76004 - 3130)

## **Warning**

Keep the probe connector clear of all solutions to avoid damages.

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807.92(a)(5)

Intended Use(s)

The ultrasound system provides imaging information used to guide the biopsy needle, through the accessory, to the anatomical site where the sample of physiological material is recovered for further analysis.

Substantial Equivalence

<i>FUTURE</i>	<i>ESAOTE Biopsy accessory for Intraoperative probe</i>	<i>Diasonics NewImage System Biopsy Attachment</i>	<i>ESAOTE AU530 Biopsy Accessory For Ultrasound Transducer K912088</i>
<b>MATERIALS</b>	Polyurethane Resin Stainless Steel	Stainless steel Medical Plastic	Stainless steel Medical Plastic
<b>NEEDLE GUIDE ANGLE</b>	Fixed	15° and 30°	20° to 45°
<b>STERILIZATION</b>	Cold Sterilization with CIDEX	Cold Sterilization with CIDEX	Cold Sterilization with CIDEX
<b>REMOVABLE OPTIONS FOR ULTRASONIC PROBE</b>	Yes	Yes	Yes
<b>FOR USE WITH VARIETY OF BIOPSY NEEDLES</b>	Yes, but needles are not supplied	Yes, needles are supplied in kit	Yes, but needles are not supplied
<b>INTENDED USE:</b> • Fine needle aspiration	Yes	Yes	Yes

Note: The biopsy attachments are not to be used for in vitro fertilization (IVF), chorionic villus sampling (CVS), or percutaneous umbilical blood sampling (PUBS).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Gerald A. Richardson  
Official Correspondent  
Biosound Esaote  
Biosound, Inc.  
8000 Castleway Drive  
Indianapolis, IN 46250

Re: K971700  
Biopsy Accessories for Intraoperative Probe  
Dated: June 19, 1997  
Received: June 20, 1997  
Regulatory class: II  
21 CFR 892.1570/Procode: 90 ITX

JUL - 9 1997

Dear Mr. Richardson:

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 Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4613. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

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**

510(k) Number (if known): 971700

Device Name: Biopsy Accessories for Intraoperative Probe

Indications for Use: The ultrasound system provides imaging information, used to guide the biopsy needle through the accessory to the anatomical site where the sample of physiological material is recovered for further analysis.

(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)

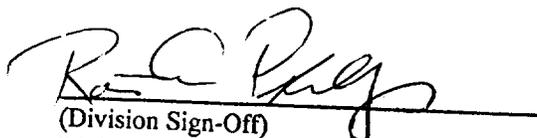
Prescription Use

X

OR

Over-The-Counter Use

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

510(k) Number 971700