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K953819

# 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)

### Submitter Information

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FDA/CDR/REGISTRATION

## 807.92(a)(2)

Trade Name: INT 13 Intraoperative Transducer

Common Name: Diagnostic Ultrasound Transducers

Classification Name(s): Transducer, Ultrasonic, Diagnostic 892.1570

## 807.92(a)(3)

### Predicate Device(s)

- Hitachi Intraoperative Ultrasound Transducer EUP - 033J K884644

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*Safety and Effectiveness Summary*  
*INT13 Intraoperative Diagnostic Ultrasound Transducer*  
*Biosound, Inc.*

807.92(a)(4)

## DEVICE DESCRIPTION

The Esaote INT13 intraoperative transducer is designed and intended to be used in open (open as opposed to laparoscopic used with a trocar) abdominal surgical procedures. More specifically, the transducer is intended to be used to image abdominal anatomy during open surgical procedures. The table below provides further descriptive information about the INT13 transducer.

### SPECIFICATIONS

Operating Temperature	+5 to +35 C°
Storing Temperature	-5 to +45 C°
Weight	0.3 Kg
Safety Requirement	IEC 601-1 (CEI62-5)
Operating Modes and Frequencies	
B - Mode	7.5 - 10.0 Mhz
M - Mode	7.5 - 10.0 Mhz
PW - Mode	3.5 - 4.7 - 7.0 Mhz
CFM	3.5 - 4.7 - 7.0 Mhz
Intended Use	Intraoperative, Abdominal
Technology	Linear Array
Cable Length	2.5 Meters

### MATERIALS

Esaote has chosen to construct the INT13 transducer with the same materials they used in constructing the LP12 Laparoscopic probe. The LP12 device is currently under review with FDA under K941935. Esaote has received FDA's letter stating that all requirements have been satisfied for part one of K941935 (two-part submission), and that FDA is awaiting only acoustic output data. The materials for the laparoscopic probe described in K941935, and those used for the subject device, INT13, are:

PVC, Putnam Plastics  
Ultem, General Electric Plastics  
FDA, TRA-Bond Epoxy

Both probes will be used in the same type of application; abdominal intraoperative imaging.

### STERILIZATION

The INT13 transducer can be sterilized with Cidex™ solutions. The procedure for sterilizing the INT13 transducer is provided in the operator's manual.

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**Intended Use(s)**

The INT13 is a diagnostic ultrasound intraoperative transducer for use in abdominal surgery. The transducer can be used to image abdominal anatomy during abdominal surgical procedures. In Doppler mode, the transducer can provide information about blood flow in abdominal vessels.

807.92(a)(6)

**Substantial Equivalence**

**SUBSTANTIAL EQUIVALENCE COMPARISON TABLE**

Characteristic	Esaote INT13	Hitachi EUP 088 J K884644
Intended Use	Abdominal, Intraoperative	Abdominal, Intraoperative
Technology	Linear Array	Linear Array
Frequencies Mhz	7.5 - 10.0	7.5
Operating Modes	B, PW, M, CFM	B, PW, M, CFM
Cable length	2.5 meters	2.2 meters
Safety Standard	IEC 601-1	IEC 601-1

The table above illustrates the equivalence of the compared devices. The intended use, and imaging characteristics of the compared products are equivalent. The Esaote product offers more frequencies than the Hitachi product which enhances the clinical utility of the Esaote product. Based on the comparison table above, we believe the two products are substantially equivalent.