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# Safety and Effectiveness Summary

JUL 23 1997

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

Gerald A. Richardson, Official Correspondent
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Contact Person: Gerald A. Richardson

Date: May 23, 1997

807.92(a)(2)

Trade Name: Sled, Finger, Handle

Common Name: Accessory for ultrasound transducer

Classification Name(s): Transducer, ultrasonic, diagnostic 892.1570

807.92(a)(3) Predicate Device(s)

| Company | Article | 510 (k) |
|---|---|---|
| Esaote | INT 13 | K953819 |
| Hitachi | EUP-033J | K884644 |

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

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*INT13 Accessories*
*Biosound Esaote*

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## Device Description

The three intraoperative probe accessories, Sled, Finger and Handle function with the AU4 ultrasound system's intraoperative probe, cleared via K953819. The intraoperative accessories consist of three kinds of plastic brackets attached to the ultrasound intraoperative transducer. The material used in the brackets has been tested following ISO 10993 / EN 30993. The biocompatibility tests required are attached.

## Specifications

| ITEM | CHARACTERISTICS | DIMENSION |
|---|---|---|
| Sled | Plastic | 47.43 mm X 22.70 mm |
| Finger | Plastic | Irregular |
| Handle | Plastic | 104.96 mm X 13.78 mm |

## Materials

The three accessories (Finger, Sled, Handle) have been designed with polyurethane resin 6090 black: Resin Polyuretanica 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
- SENSITIZATION
- IRRITATION

These tests where performed by **Biolab** the Italian Laboratory located in Milan at Vimodrone Via Buozzi 2 tel +39-2-250715-1 in accordance with ISO10993.

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## Sterilization

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

Recommended sterilizing solution.

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

**Warning**

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

807.92(a)(5)

## Intended Use(s)

The ultrasound system used with the Intraoperative Transducer provides imaging information. Through the accessory previously described, the surgeon is able to position the probe more easily inside the body during the surgical procedure. The probe and its various accessories may also be used in Vascular and Small Parts imaging applications. These applications were cleared via K944485/S3.

807.92(a)(6)

## Substantial Equivalence

Other manufacturers market separate dedicated ultrasound probes for each one of the configurations which are provided by the Esaote accessories. With these accessories, the user achieves a variety of different configurations with a single probe. The following table shows a comparison between the intraoperative probe and each accessory with a predicate ultrasound transducer, already on the market.

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| | *Esaote INT13 Accessories* | *Esaote INT13* | *Hitachi EUP-033J* |
|---|---|---|---|
| **MATERIALS** | Plastic | Plastic | Plastic |
| **STERILIZATION** | Cold Sterilization with Cidex | Cold Sterilization with Cidex | Cold Sterilization |
| **INTENDED USE** | Abdominal, intraoperative | Abdominal, intraoperative | Surgery/vascular |
| **ACCESSORIES** | Subject to this submission | No | Yes |

DEPARTMENT OF HEALTH & HUMAN SERVICES · Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 1997

Gerald A. Richardson
Biosound Easote
8000 Castleway Drive
Indianapolis, IN 46250

Re: K971942
Sled, Finger, Handle (Accessories for Ultrasound Transducer)
Dated: May 23, 1997
Received: May 27, 1997
Regulatory class: II
21 CFR 892.1570/Procode: 90 ITX

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

510k 971942

Accessories for Intraoperative Probe
INT 13

Indications for Use Form

**Fill out one form for each ultrasound system and each transducer.**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation: A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|---|---|---|---|---|---|---|---|---|---|---|
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intra-operative (Specify) | | X | | | | X | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (Specify) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Luminal | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal Conventional | | | | | | | | | | |
| Musculo-Skeletal Superficial | | | | | | | | | | |
| Extracorporeal Other (Specify) | | X | | | | X | | | | |

Additional Comments: Designed to assist in the manipulation of the INT 13 probe in intraoperative and extracorporeal procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971942

X Prescription Use (Per 21 CFR 801.109)