

**510(k) Summary  
for  
TERATECH Model 2000 Imaging System**

**1. SPONSOR**

Teratech Corporation  
223 Middlesex Turnpike  
Burlington, MA 01803

Contact Person: Alice Chiang, President  
Telephone: 781-270-4143

Date Prepared: July 26, 1999

**2. DEVICE NAME**

Proprietary Name: TERATECH Model 2000 Imaging System  
Common/Usual Name: Diagnostic Ultrasound Imaging System  
Classification Name: Ultrasonic Pulsed Echo Imaging System (21 CFR  
892.1560, 90-IYO)  
Diagnostic Ultrasound Transducer (21 CFR 892.1570,  
90-ITX)

**3. PREDICATE DEVICES**

ATL High-Definition Imaging UltraMark-9 (K903603)  
B&K 3535 (K914945)  
Tetrad 2300 E/U (K946277)

**4. INTENDED USE**

The TERATECH Model 2000 is intended for abdominal, pelvic, cardiac, peripheral vascular, neurovascular, and fetal imaging.

**5. DEVICE DESCRIPTION**

The TERATECH Model 2000 is a portable ultrasound imaging system with grayscale or brightness (B-Mode) imaging. The Model 2000 consists of a laptop computer and a 3 MHz linear array ultrasonic probe. Technical specifications for the Model 2000 are as follows:

|                            |  |
|----------------------------|--|
| System frequencies:        | 2-4 MHz  |
| Frame rate:                | 15-30 fps (imaging only)                                 |
| Number of ultrasound lines |  |
| per frame:                 | 128  |
| Fields of view:            | 2-27 cm  |
| Mode of Operation:         | 2D imaging   |
| Image display:             | Rectangular and trapezoidal                              |
| Video:                     | S-VHS Output, External VGA Monitor                       |
| LCD size:                  | 14.1"  |
| Gray shades:               | 256  |
| Image magnification:       | 1X-4X, probe dependent                                   |
| Image presentation:        | black/white, left/right, up/down                         |
| Image processing:          | gamma correction, dynamic range, speckle noise reduction |
| Input power:               | 115 VAC, A/C adapter rated @ 60 W                        |
| Power consumption:         | < 20 W   |
| Leakage current:           | 50 $\mu$ A max   |
| Primary breakdown voltage: | 2500 V AC min  |
| Size:                      | Width: 12.2"<br>Height: 10"<br>Depth: 2"                 |
| Weight:                    | 12 lb (laptop and probe)                                 |

## 6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The TERATECH Model 2000 is substantially equivalent to other diagnostic ultrasound devices currently in commercial distribution in the United States. Examples of these devices are the ATL High-Definition Imaging UltraMark-9 (K903603), the B & K 3535 (K914945), and the Tetrad 2300 E/U (K946277). The Model 2000 has the same intended uses as each of these predicates and offers similar operating features. The main differences between the Model 2000 and the predicate devices are the compact size and low power consumption of the Model 2000.



NOV 10 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Teratech Corporation  
Sheila Hemeon-Heyer  
Senior Staff Consultant  
c/o Medical Device Consultants, Inc.  
49 North Plain Street  
North Attleboro, MA 02740

Re: K992505  
Teratech Model 2000 Imaging System  
Dated: September 29, 1999  
Received: September 30, 1999  
Regulatory Class: II  
21 CFR 892.1560/Procode: 90 IYO

Dear Ms. Hemeon-Heyer:

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 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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Teratech Model 2000 Imaging System, as described in your premarket notification:

Transducer Model Number

L3 (3 MHz Linear Array)

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 Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. 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 at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

*for Daniel G. Schultz*

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosures

**Diagnostic Ultrasound Indications for Use Form  
Teratech Model 2000 Imaging System**

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 | Amplitude Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
| Ophthalmic                    |                   |   |   |     |     |               |                   |                        |                    |                 |
| Fetal                         |                   | N |   |     |     |               |                   |                        |                    |                 |
| Abdominal                     |                   | N |   |     |     |               |                   |                        |                    |                 |
| Intraoperative (Specify)      |                   |   |   |     |     |               |                   |                        |                    |                 |
| Intraoperative Neurological   |                   |   |   |     |     |               |                   |                        |                    |                 |
| Pediatric                     |                   | N |   |     |     |               |                   |                        |                    |                 |
| Small Organ(Specify)          |                   |   |   |     |     |               |                   |                        |                    |                 |
| Neonatal Cephalic             |                   | N |   |     |     |               |                   |                        |                    |                 |
| Adult Cephalic                |                   | N |   |     |     |               |                   |                        |                    |                 |
| Cardiac                       |                   | N |   |     |     |               |                   |                        |                    |                 |
| Transesophageal               |                   |   |   |     |     |               |                   |                        |                    |                 |
| Transrectal                   |                   |   |   |     |     |               |                   |                        |                    |                 |
| Transvaginal                  |                   |   |   |     |     |               |                   |                        |                    |                 |
| Transurethral                 |                   |   |   |     |     |               |                   |                        |                    |                 |
| Intravascular                 |                   |   |   |     |     |               |                   |                        |                    |                 |
| Peripheral Vascular           |                   | N |   |     |     |               |                   |                        |                    |                 |
| Laparoscopic                  |                   |   |   |     |     |               |                   |                        |                    |                 |
| Musculo-skeletal Conventional |                   |   |   |     |     |               |                   |                        |                    |                 |
| Musculo-skeletal Conventional |                   |   |   |     |     |               |                   |                        |                    |                 |
| Musculo-skeletal Superficial  |                   |   |   |     |     |               |                   |                        |                    |                 |
| Other (Specify)               |                   |   |   |     |     |               |                   |                        |                    |                 |

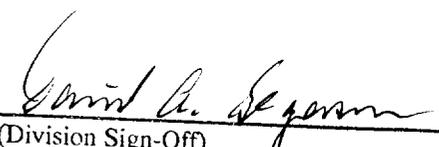
N = new Indication; P = previously cleared by FDA; E=added under Appendix E

**Additional Comments:** For use with 3 MHz Model L3 Transducer.  
Intended for use in military field settings in addition to hospital/clinic settings.

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

Concurrence of CDRH, Office of Device Evaluation

Prescription Use (Per CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K992505

**Diagnostic Ultrasound Indications for Use Form  
3 MHz Model L3 Transducer for  
Teratech Model 2000 Imaging System**

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 | Amplitude Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
| Ophthalmic                    |                   |   |   |     |     |               |                   |                        |                    |                 |
| Fetal                         |                   | N |   |     |     |               |                   |                        |                    |                 |
| Abdominal                     |                   | N |   |     |     |               |                   |                        |                    |                 |
| Intraoperative (Specify)      |                   |   |   |     |     |               |                   |                        |                    |                 |
| Intraoperative Neurological   |                   |   |   |     |     |               |                   |                        |                    |                 |
| Pediatric                     |                   | N |   |     |     |               |                   |                        |                    |                 |
| Small Organ(Specify)          |                   |   |   |     |     |               |                   |                        |                    |                 |
| Neonatal Cephalic             |                   | N |   |     |     |               |                   |                        |                    |                 |
| Adult Cephalic                |                   | N |   |     |     |               |                   |                        |                    |                 |
| Cardiac                       |                   | N |   |     |     |               |                   |                        |                    |                 |
| Transesophageal               |                   |   |   |     |     |               |                   |                        |                    |                 |
| Transrectal                   |                   |   |   |     |     |               |                   |                        |                    |                 |
| Transvaginal                  |                   |   |   |     |     |               |                   |                        |                    |                 |
| Transurethral                 |                   |   |   |     |     |               |                   |                        |                    |                 |
| Intravascular                 |                   |   |   |     |     |               |                   |                        |                    |                 |
| Peripheral Vascular           |                   | N |   |     |     |               |                   |                        |                    |                 |
| Laparoscopic                  |                   |   |   |     |     |               |                   |                        |                    |                 |
| Musculo-skeletal Conventional |                   |   |   |     |     |               |                   |                        |                    |                 |
| Musculo-skeletal Conventional |                   |   |   |     |     |               |                   |                        |                    |                 |
| Musculo-skeletal Superficial  |                   |   |   |     |     |               |                   |                        |                    |                 |
| Other (Specify)               |                   |   |   |     |     |               |                   |                        |                    |                 |

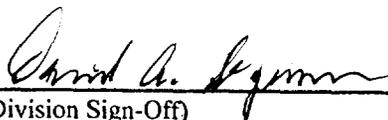
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Prescription Use (Per CFR 801.109)



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