



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 18 2001

Mr. Genshiro Ogawa  
President  
Elltec Company Limited  
Shirakawa No. 6 Bldg. Rm. 206  
2-18-5, Nishiki, Naka-Ku  
Nagoya,  
JAPAN

Re: K012906  
Trade/Device Name: Animec, Models AM-2S-4 and AM-2S-5  
Regulation Number: None  
Regulation Name: Warmer, Infusion Fluid and Blood  
Regulatory Class: II  
Product Code: BSB and LGZ  
Dated: October 9, 2001  
Received: October 3, 2001

Dear Mr. Ogawa:

This letter corrects our substantially equivalent letter of October 9, 2001 regarding the regulation name.

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 enclosures) 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.

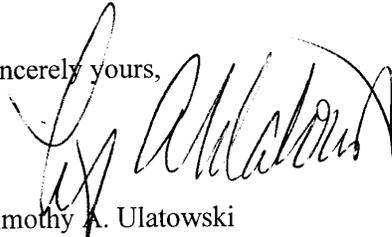
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation

(QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, 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 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 continue 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) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**ELLTEC**

**ELLTEC CO., LTD.**

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Date . . . . .

September 25, 2001

Applicant: Elltec Co., Ltd.

510(k) Number: K012906

Device Name: Infusion/blood warmer ANIMEC AM-2S-4, AM-2S-5

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Indications For Use:

The infusion/blood warmer model ANIMEC AM-2S is an electrically powered, dry warmer which supplies external heat to the plastic tubing incorporated in intravenous administration sets for intermittent use and low flow rate applications at 1 to 12ml/min. The AM-2S is available in two sizes: 4mm channel for I.V. administration sets and a 5mm channel for blood administration sets.

Sincerely,  
Elltec Co., Ltd.



Genshiro Ogawa  
President

Ueda Hidenori  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K012906