DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1999

Mr. Jay W. Taylor
Executive Vice President
Nortrade Medical, Inc.
9382 South 670 West
Sandy, Utah 84070

Re: K990181
Trade Name: Burnfree Fire/Trauma Blanket
Classification Regulation Name: Burn Sheet
Regulatory Class: I
Product Code: FPY
Dated: July 20, 1999
Received: July 26, 1999

Dear Mr. Taylor:

We have reviewed your premarket notification submission and have found this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). Therefore, you may immediately begin marketing this device as described in your premarket notification.

The final classification regulation for your device appears in Title 21 of the Code of Federal Regulations (CFR) 880.5180. We suggest that you review this regulation since it may grant other exemptions from certain general controls of the Act. Your device's product code, classification regulation name and regulatory class are shown above. When listing your device with the Food and Drug Administration, please use this product code.

In the future, new but substantially equivalent devices which fall within the above classification regulation name and meet the classification criteria may be marketed without sending a premarket notification submission to the Food and Drug Administration. We suggest, however, that you review 21 CFR Section 878.9 to determine whether or not your new device(s) meets the limitations of exemption from Section 510(k) of the Act.

If you have any questions regarding this letter, please contact Gail Gantt at (301) 594-3090 or the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health