



MANUFACTURER ROUTE 22
 SOMMERVILLE NJ 08876

ACCESS NUMBER M125866

PRODUCT CODE

PANEL GENERAL AND PLASTIC
 SURGERY

REPORT TYPE SERIOUS INJURY

DATE FDA RECEIVED 07/15/1986

DEVICE CATALOGUE NUMBER W31G

EVENT DESCRIPTION TYPE FINAL

EVENT DESCRIPTION

"STERNUM INFECTION 4 DAYS POST-OP REQUIRED RE-EXPLORATION."

CLOSEOUT TEXT

THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. IN ADDITION, AVAILABLE FREQUENCY AND SEVERITY DATA DO NOT INDICATE THAT ANY FURTHER INVESTIGATION IS NECESSARY AT THIS TIME. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED.