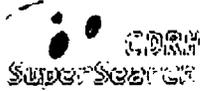




CENTER FOR DEVICES AND RADIOLOGICAL HEALTH



MANUFACTURER	US ROUTE 22 SOMMERSVILLE NJ 08876
ACCESS NUMBER	M154511
PRODUCT CODE	
PANEL	ORTHOPEDIC
REPORT TYPE	SERIOUS INJURY
DATE FDA RECEIVED	05/20/1988
DEVICE CATALOGUE NUMBER	W31G
EVENT DESCRIPTION TYPE	FINAL

EVENT DESCRIPTION

REOPERATION FOLLOWING A BONE GRAFT FROM THE ILIAC CREST DUE TO POST-OP DRAINAGE (A CLEAR SEROUS DRAINAGE). THE SMEAR FROM THE FLUID WAS NEGATIVE FOR INFECTION, THE DR, DURING SURGERY, SCRAPED AWAY THE BONE WAX AND THE DRAINAGE SUBSIDED.

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.