Medtronic Sofamor Danek
Magellan™ Autologous Platelet Separator System
(as required by 21 CFR 807.92)
510(k) Summary – BK040068
September 2004

Submitter:	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, TN 38132
Contact Person:	Richard Treharne Sr. Vice President Regulatory Affairs
Trade Name:	Magellan™ Autologous Platelet Separator System
Classification Name:	General purpose laboratory equipment labeled or promoted for a specific medical use (21 CFR 862.2050)
Predicate Devices:	Symphony Bone Graft Delivery System (022246), DePuy AcroMed Inc. and itself, the Magellan™ Autologous Platelet Separator System (BK030040).
Device Description:	The Magellan™Autologous Platelet Separator System consists of a microprocessor controlled table-top centrifuge and processing disposables designed to allow for safe and rapid automatic separation of plasma and platelets. The centrifuge spins at a maximum speed of 3800 rpms at the maximum g-force of approximately 1300s.
Intended Use:	The MAGELLAN™ Autologus Platelet Separator System is designed to be used in the clinical laboratory or intraoperatively at the point of care for the safe and rapid preparation of platelet poor plasma and platelet concentrate (platelet rich plasma) from a small sample of a mixture of blood and bone marrow. The plasma and concentrated platelets produced can be used for diagnostic tests. Additionally, the platelet rich plasma can be mixed with autograft and/or allograft bone prior to application to an orthopedic site
Functionality & Safety Testing:	Performance verification testing was performed on the subject device by Medtronic Biologic Therapeutics and Diagnositics Research and Development and was included in this submission.
Substantial	

Equivalence: The Magellan™ Autologous Platelet Separator System is substantially equivalent to the noted predicate devices based on the similarities of technological characteristics, indications for use and test results.