



**Acknowledgment and Consent for Disclosure of  
an 18 U.S.C. §208 Particular Matter Waiver**

SGE: Edward N. Hanley, Jr., M.D.  
Committee: Orthopaedic and Rehabilitation Devices Panel of FDA’s Medical Devices Advisory  
Committee  
Meeting Date(s): July 17, 2007

I acknowledge that contingent upon public disclosure of the following financial interests submitted on my FDA Form 3410 and related to the agenda item: a premarket approval application submitted by Medtronic Sofamor Danek for the Bryan Cervical Disc Prosthesis. This device is indicated in skeletally mature patients with cervical degenerative disc disease (DDD) at one level from C3-C7, I am eligible to receive a particular matter waiver under 18 U.S.C. §208.

Type of Interest	Involvement	Magnitude
Stock	Parent of the sponsor	from \$25,001 to \$50,000
Grant	SGE’s institution involved in sponsor’s product study; SGE is not involved in data generation or analysis	less than \$100,000

I hereby request that FDA make this information publicly available on my behalf at the start of the advisory committee meeting for which it is issued by reading the statement into the record at the time of the meeting. I understand that without public disclosure of the interest, the waiver is not valid.

\_\_\_\_\_/S/  
Signature

06/06/07  
Date