



Medtronic

SOFAMOR DANEK

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Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

October 12, 2006

**Re: P050053 INFUSE® BONE GRAFT for Oral Maxillofacial Bone Grafting
Procedures Amendment 8**

Dear Sir or Madam:

Per our discussion and your email of October, 6, 2006, we have modified our Indications for Use Statement. We believe that this statement is consistent with the inclusion and exclusion criteria defined in our IDE studies, and adequately defines our target population.

The new indication for use is:

INFUSE® Bone Graft is indicated as an alternative to autogenous bone graft for sinus augmentations and localized alveolar ridge augmentations for defects associated with extraction sockets.

An original and nine copies of this amendment are provided.

The existence of the PMA and the data and other information that it contains are confidential, and the protection afforded to such confidential information by 18 USC 1905, 21 USC 331(j), 5 USC 552, and other applicable laws is hereby claimed.

If there are any questions regarding this submission please contact me via phone at

Sincerely,

Edward S. Chin D.Ph., MBA
Group Director, Regulatory and Clinical