



FILE COPY

January 25, 2002

Mark Bleyer, President
Cook Biotech Incorporated
3055 Kent Avenue
West Lafayette, IN 47906

Dear Mr. Bleyer:

Your petition requesting the Food and Drug Administration to reconsider its December 19, 2001 determination that the 510(k) premarket notification for the SURGISIS Periodontal Membrane (D.C. #K010952) could not be evaluated for substantial equivalence without clinical data demonstrating efficacy for the indications to be cleared and resorption characteristics of the device was received by this office on 01/25/02. It was assigned docket number 02P-0045/PRC 1 and it was filed on 01/25/02. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

cc: Ted Heise, Ph.D.
Med Institute
1400 Cumberland Avenue
West Lafayette, IN 47906

02P-0045

ACK 1