FDA CDRH General and Plastic Surgery Devices Advisory Committee Meeting

May 31, 2019

Gaithersburg Holiday Inn,
Grand Ballroom,
2 Montgomery Village Ave.,
Gaithersburg, MD 20879

As required by section 513(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food and Drug Administration (FDA) is convening the General and Plastic Surgery Devices Advisory Panel (the Panel) for the purposes of obtaining recommendations about the reclassification of collagen-based hemostatic devices.

FDA is holding this panel meeting to obtain input on the risks and benefits of collagen-based hemostatic devices. The Panel will be asked to recommend to FDA whether collagen-based hemostatic devices should be down classified from Class III (subject to Premarket Approval) into Class II (subject to General and Special Controls). The Panel will be asked to discuss the types of evidence (including clinical evidence) that would be helpful to support certain indications as well as appropriate controls necessary to mitigate the risks to health and assure the safety and effectiveness of these devices.

AGENDA – Collagen Based Hemostatic Devices

8:00 a.m.	Call to Order, Opening Remarks and Introduction of the Committee	Panel Chair
8:05 a.m.	Conflict of Interest Statement	Designated Federal Officer
	Introduction	
8:15 am	Introductory Remarks & Device Description	Adam Pierce, Ph.D.
8:35 am	Clarifying Questions from the Panel	
	External Speaker Presentations	
8:45 a.m.	Industry Presentations	
9:45 a.m.	Clarifying Questions from the Panel	
	FDA Presentations	
9:55 a.m.	Clinical Considerations of Absorbable Collagen-based Hemostats	George Gibeily, M.D., F.A.C.S.
10:15 a.m.	Clarifying Questions from the Panel	
10:25 a.m.	Break	
10:40 a.m.	Post-market Surveillance for Absorbable Collagen-based Hemostats	Karen Nast, M.S., R.N.
11:00 a.m.	Clarifying Questions from the Panel	
11:10 a.m.	Proposed Reclassification & Special Controls	Adam Pierce, Ph.D.
11:30 a.m.	Clarifying Questions from the Panel	
11:40 a.m.	Lunch	
	Open Public Hearing	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Clarifying Questions from the Panel	
	FDA Questions	
2:10 p.m.	Questions to the General and Plastic Surgery Devices Panel	
4:00 p.m.	Adjournment	