



**FOOD AND DRUG ADMINISTRATION**  
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

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MEMORANDUM

**DATE:** Tuesday, September 4, 2012  
2:00 PM

**WHERE:** WOC 1 room 424 N

**SUBJECT:** Telecon Record for EVARREST (STN 125392/0)

**SPONSOR:** Ethicon, Inc.

**TO:** File for STN 125392/0, EVARREST

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**CBER representatives:**

Nisha Jain, MD, Chief, Clinical Review Branch  
Tim Lee, PhD, Acting Chief, Laboratory of Hemostasis  
Kimberly Lindsey, MD, Medical Officer, Clinical Review Branch  
Natalya Ananyeva, PhD, Senior Staff Fellow, Laboratory of Hemostasis

**CDRH: Herbert Lerner, MD**

Supervisory Medical Officer, CDRH / ODE / Division of Reproductive, Gastro-Renal and Urological Devices / Ob Gyn Devices Branch. Dr. Lerner was not able to find his Branch Chief, Dr. Elaine Blyskun, to join in the telecon.

**Issue:**

A consultative review with CDRH regarding the BLA STN 125392/0, EVARREST Fibrin Sealant Patch, submitted by ETHICON, raised concerns about the -b(4)----- component of EVARREST.

Specifically, CDRH noted that the oxidized regenerated cellulose (ORC) component in EVARREST is ---b(4)-----  
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CDRH wants CBER to understand that in the presence of blood—b(4)-----  
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CBER noted that the proposed package insert for EVARREST already includes a warning and precautions statement about the possible formation of adhesions.

