

**510(k) Summary**

**Date Prepared:** November 17, 2017

**Submitter:** Cascade Medical Enterprises, LLC  
207 Pinot Court  
Chapel Hill, NC 27517

**Contact Person:** Nicholas A. Grippi  
Phone: (984) 888-5532  
E-Mail: Nicholas.Grippi@ATT.net

**Device Trade Name:** Cascade Medical FIBRINET® System

**Common Name:** Platelet and Plasma Separator for Bone Graft Handling  
**Classification Name:** Automated Blood Cell Separator (21 CFR 864.9245)  
**Regulatory Class:** Class II  
**Product Code:** ORG

**Substantial Equivalence:** The device in this submission is identical to the device cleared under BK120009.

**Device Description:** The Cascade Medical FIBRINET® System is a single-use, sterile kit consisting of two or more evacuated blood collection tubes, needles and a transfer device. Peripheral blood is collected in the evacuated tubes and centrifuged to obtain platelet rich plasma (PRP).

**Indications for Use:** The Cascade Medical FIBRINET® System is indicated for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of peripheral blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to the application to a bony defect for improving handling characteristics.

**Technology Aspects:** The evacuated, sterile tubes have a vacuum which facilitates the collection of peripheral blood. Blood components are separated and concentrated by density using a standard, general purpose centrifuge.