

## **510(k) Summary**

**Submitter:** Cascade Medical Enterprises, LLC  
20 Greenup Court  
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**Contact Person:** Nicholas Grippi

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

**Common Name:** Blood Specimen Collection Devices

**Classification Name:** General Purpose Laboratory Equipment Labeled or Promoted for a Specific Medical Use  
21 CFR 862.2050

**Substantial Equivalence:** The proposed device is substantially equivalent to other blood specimen collection devices previously cleared by the FDA via the 510(k) Notification process.

**Device Description:** The Cascade Medical FIBRINET™ System is a self-contained disposable kit. Each kit consists of two or more sterile evacuated blood collection tubes, needles and a transfer device.

**Intended Use:** The Cascade Medical FIBRINET™ System is designed to be used for the safe and rapid preparation of autologous platelet-rich-plasma (PRP) from a small sample of blood at the patient point of care. The PRP can be mixed with autograft and allograft bone prior to application to an orthopedic surgical site as deemed necessary by the clinical use requirements.

**Technological Aspects:** The proposed device has the same technological characteristics and is similar in design to the predicate devices previously cleared via the 510(k) Notification process.