

Indications for Use (CBER/OTAT)

510(k) Number (if known): BK170096

Device Name: Cascade Medical Fibrinet® System

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 application to a bony defect for improving handling characteristics.

Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CBER, Office of Tissues and Advanced Therapies

Office Sign-Off
Office of Tissues and Advanced Therapies

510(k): _____