



HAIR DISORDERS

COMPARISON OF FOOD AND DRUG ADMINISTRATION CLEARED PLATELET RICH PLASMA DEVICES

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Introduction: Platelet-rich plasma (PRP) may be effective in the treatment of hair diseases and skin rejuvenation through growth factor-induced cell proliferation and anti-inflammatory action. Numerous centrifuges have been used to isolate PRP for alopecia and skin rejuvenation; however, to date, no study has evaluated whether the use of different centrifuges has any implications on the PRP product. Herein, we performed a FDA 510(k) database search and characterized centrifuges available on the market for PRP.

Objective: To describe differences in PRP device characteristics including volume collection, separation methods, and product yield.

Materials and Methods: A search of the FDA product code builder to identify the regulatory codes for devices separating PRP from whole blood was performed. The following codes for PRP devices were utilized: "JQC", class I, under Chemistry: Centrifuges (Micro, Ultra, Refrigerated) For Clinical Use and "ORG", class II, under Hematology: Platelet and Plasma Separators for Bone Graft Handling". An internet search of each device's associated website was then conducted to obtain information on their respective PRP collection process and content.

Results: Search of the 510(k) database on September 12, 2018, returned 72 devices cleared from 1976 to 2018. An Internet search produced information for 34 devices, which use single or double rounds in a centrifuge, with or without a separating medium. The devices use 8-180mL of blood per session and yield approximately 6-22mL of PRP.

Conclusions: Design, sample collection, and separation methods vary across PRP centrifuges that are FDA-cleared in the United States. This variation may affect the clinical data being reported in the literature regarding the efficacy of PRP for treating either hair disease or skin rejuvenation. Future research is needed to understand and standardize the elements of an optimal PRP device design and collection parameters.

