

BK 000037

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**510(k) Summary for the
Harvest Technologies PRP Separation System**

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Device Trade Name: Harvest PRP Separation System

Common name: General Purpose Centrifuge

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 table-top centrifuges previously cleared by the FDA via the 510(k) Notification process

Device Description: **Harvest PRP Separation System:** Includes a table-top, self-decanting, swinging bucket centrifuge and processing disposable designed to allow for rapid automatic separation of plasma and platelets. The centrifuge spins at a maximum speed of 3650 rpms at a maximum force of approximately 1500 g.

Intended Use: The Harvest Technologies PRP Separation 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's 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 Characteristics: The proposed device has the same technological characteristics and is similar in design and configurations compared with the predicate devices (See Table 6-1).

TABLE 6-1
COMPARISON OF THE HARVEST PRP SEPARATION SYSTEM with the
SORVALL TECHNOSPIN and 3i CELSEP CENTRIFUGES

Features	Harvest PRP Prep. System (This Submission)	3i CelSep (K994148)	Technospin (K860747)
Principle of Operation	Separation based on density of liquids	Separation based on density of liquids	Separation based on density of liquids
Table-Top	Yes	Yes	Yes
Refrigerated	No	No	No
Swinging Bucket	Yes	Yes	Yes
Automatic Decanting	Yes, plasma automatically decanted to plasma chamber	No, requires manual expression of plasma to satellite bag	No, requires manual aspiration of plasma from open centrifuge tube
Micro-processor Controlled	Yes	Yes	Yes
User Programmable	No, program set by manufacturer	Yes	Yes
Speed Control	Preset	Selectable	Selectable
Acceleration and Braking	Current-controlled	Current-controlled	Current-controlled
Maximum RPM	3650 RPM	3400 RPM	4000 RPM
Maximum RCF	1500 G	2050 G	3077 G
Tube Capacity	One or Two Processing Disposables (max. 60 mL/disposable)	1 Disposable 60ml/disposable	Variety of sizes and volumes up to 250mL
Lid Locking, Lid Holding	Yes	Yes	Yes
Imbalance Detector	Yes	No	Yes
Construction	Anti-torsion construction, metal housing and rotor	Anti-torsion construction, metal housing and rotor	Anti-torsion construction, metal housing and rotor