

Indications for Use

510(k) Number (if known)

BK210632/0

Device Name

Royal MAXX™ PRP Concentration System

Indications for Use (Describe)

The Royal MAXX PRP Concentration System is designed to be used at the patient's point of care for the safe and rapid preparation of a platelet rich plasma (PRP) from a small sample of a mixture of peripheral blood and bone marrow aspirate that is mixed with autograft and or allograft bone prior to application to a bony defect for improving handling characteristics.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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