



ROYAL BIOLOGICS

Vendor Supplier Information

support@royalbiologics.com

www.royalbiologics.com

Tel: 201.488.1549

Fax: 270.721.6932



401 Hackensack Ave, #604 • Hackensack, NJ 07601

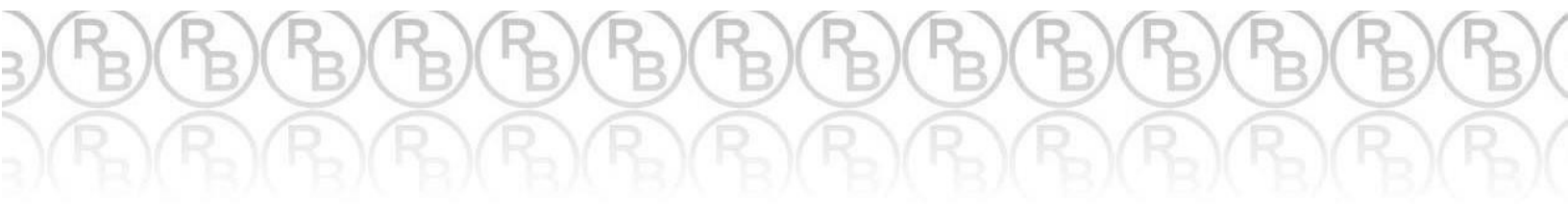


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About Us

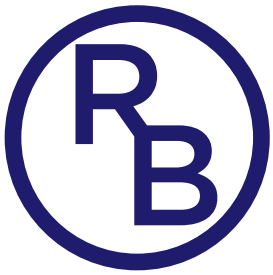
Royal is an orthobiologics & life science company that develops, produces and distributes products for orthopedic, sports medicine, spine and regenerative medicine applications. The Company is based in Jersey City, New Jersey.

Its products include proprietary sterile disposable systems for stem cell procedures (platelet rich plasma (PRP) and bone marrow aspirate (BMA) in regenerative medicine), orthobiologics for surgical procedures (synthetic bone graft substitutes, novel allografts, demineralized bone products, bone chips and amniotic membrane stem cells) and hardware products for the spinal implant and interbody fusion industry (plating systems, lumbar cages systems, pedicle screws and interbody cages).



ROYAL
BIOLOGICS

WWW.ROYALBIOLOGICS.COM



**ROYAL
BIOLOGICS**

MAXX™ *CONCENTRATION SYSTEM*



The Next Generation in Regenerative Cellular Technology



• Maxx PRP

• Maxx BMC

The Next Generation in Regenerative Medicine Technology.

Customizable PRP at Your Fingertips to treat a variety of conditions.



Maxx-PRP provides a 4-6x level over baseline concentration of platelets, promoting the following growth factors:

VEGF - Vascular Endothelial Growth Factors

PDGF - Platelet Derived Growth Factors

TGF - Transforming Growth Factors

Maxx™ PRP & Maxx™ BMC

Features

- Dual spin capability in one device
- Allows clinicians to adjust hematocrit levels
- 8 minute processing time within a closed, sterile system
- Faster cell collection with less clotting
- Access "Buffy Coat" layer in seconds
- Delivers LP - PRP and LR - PRP
- Ability to process up to 240cc of PRP or BMC in one spin cycle





Sports Medicine with Maxx PRP™

PRP or (Platelet Rich Plasma) is used to treat soft tissue repair in sports medicine injuries such as osteoarthritis and tendinosis. This is a result from the overuse or damage to collagen fibers that make up your bodies tendons. Common injuries are seen in “sprains, strains, pulls and tears” of the body’s foot, ankle, knee and elbow. This damaged tissue does not heal properly by itself due to poor blood supply.

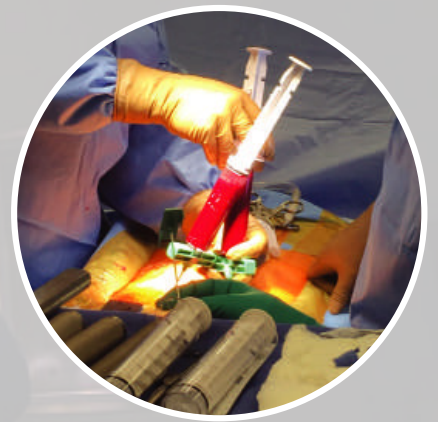
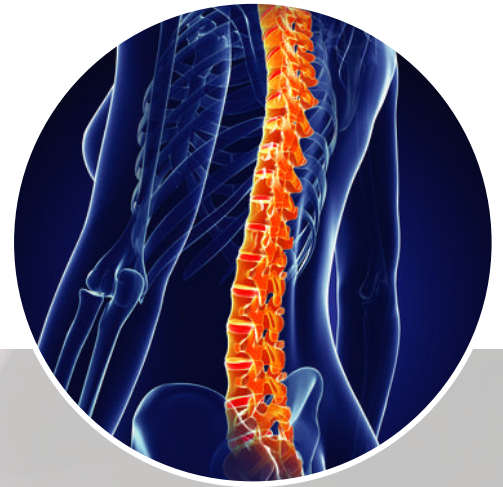
The concentrated platelets found in PRP contain bioactive proteins that help repair, heal and regenerate damaged tissue. PRP helps promote growth and repair by stimulating the development of new blood cells. By providing concentrated platelets and new blood flow to damaged areas, the body develops new collagen fibers. These collagen fibers have potential to heal and repair the damaged tissue.



With MAXX PRP™, clinician’s can provide the optimal concentrated PRP to help heal their patients specific conditions. Maxx PRP™’s lead screw technology allows the clinician to treat with either Leukocyte Rich or Leukocyte Poor PRP. Maxx PRP™ has the ability to deliver a 4-6X concentrated product over baseline within 8 minutes, in 2 concentrated cycles. Maxx PRP™ allows the user to concentrate 25-240cc of peripheral blood. Average final product volume yield is 7-10%.

ORTHOPEDICS with Maxx™ BMC

Bone marrow concentrate (BMC) is widely used and recognized now in orthopedics as a complement to help facilitate mature bone growth. Bone-marrow aspirate is a rich source of cells, cytokines, and growth factors. Concentrating bone marrow accelerates the ability to harness these viable growth factors that are needed for bone formation.



Maxx BMC allows clinicians to provide a concentrated final product within 8 minutes. Maxx's (Lead Screw Technology) allows clinicians to maximize their opportunity to grab essential growth factors from the "Buffy Coat" layer on 2 spin cycle attempts. Harnessing these viable cells in 2 spin cycles after concentration provides a more optimal product to compliment bone formation. Maxx BMC allows the user to concentrate 25-240cc of autologous bone marrow aspirate, in one centrifugation. Average final product volume yield is 7-10%.



What is Lead Screw Technology?

Maxx's Lead Screw technology allows clinicians to pinpoint precise and accurate areas of the buffy coat (growth factor layer) of PRP or BMC concentrate in a matter of seconds. Up to two concentrated cycles can be conducted in 8 minutes, yielding 4-6X platelet concentrations over baseline. This gives the clinician the advantage to customize the final product based on procedure specific needs.

Sterile Closed System – Dual Concentrations, One Device

Sterility is key in all clinical settings. Unlike other systems, Maxx's Lead Screw Technology allows clinicians to concentrate up to 2 cycles with one device. This eliminates the need to transfer concentrated cells to a 2nd device and prevents further contamination with unsterile breaks and transfers.

The Next Step in Regenerative Cellular Technology

The Maxx Concentration Systems gives clinicians the ability to deliver a safe, effective product in a matter of minutes in any clinical setting. With Lead Screw Technology, Maxx PRP and Maxx BMC provide clinicians a new option to treat a variety of conditions with a safer, faster and more efficient approach





Who We Are

Royal Biologics is an Orthobiologics company specializing in the research and advancement of Regenerative Cellular Therapy. Our primary focus is using autologous bioactive cells to help promote healing in a wide range of clinical settings. We believe in harnessing the power of cellular therapy to maximize our bodies potential.

Product Information

- MXPRP -1 Maxx PRP concentration system
- MXBMC60 - Maxx BMC Concentration System 60ml
- MXBMC120 - Maxx BMC Concentration System 120ml



Royal Biologics
401 Hackensack Ave, #604
Hackensack NJ 07601

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SUBSTANTIALLY EQUIVALENT

April 16, 2021

Royal Biologics, Inc
Attn: Adam Ferretti, PhD
Director of Quality
401 Hackensack Avenue, #604
Hackensack, NJ 07601

Re: BK210563

Trade/Device Name: Royal Maxx Autologous PRP Concentration System

Regulation Number: 21 CFR 864.9245

Regulation Name: Automated blood cell separator

Regulatory Class: Class II

Common Name: Platelet and Plasma Separator for Bone Graft Handling

Product Code: ORG

Dated: March 5, 2021

Received: March 5, 2021

Dear Dr. Ferretti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CBER does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)

1/11/2022

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER HAUSER 5905 E. Galbraith Rd, Ste 9000 Cincinnati OH 45236	CONTACT NAME: Ashlie Rutherford	
	PHONE (A/C No. Ext): 513-745-9200	FAX (A/C, No):
E-MAIL ADDRESS: arutherford@thehausergroup.com		
INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A : THE TRAVELERS INS CO		87726
INSURED Royal Biologics Inc. Alpha Spine Corp. AR Orthopedic Holdings, LLC 401 Hackensack Avenue Suite 604 Hackensack NJ 07601	INSURER B : Travelers Property Casualty Co of America	25674
	INSURER C : Travelers	25658
	INSURER D :	
	INSURER E :	
INSURER F :		

COVERAGES

CERTIFICATE NUMBER: 196712611

REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
C	<input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY <input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: <input checked="" type="checkbox"/> POLICY <input type="checkbox"/> PRO-JECT <input type="checkbox"/> LOC OTHER:			ZLP16N72627	1/15/2022	1/15/2023	EACH OCCURRENCE \$ 1,000,000 DAMAGE TO RENTED PREMISES (Ea occurrence) \$ 300,000 MED EXP (Any one person) \$ 10,000 PERSONAL & ADV INJURY \$ 1,000,000 GENERAL AGGREGATE \$ 2,000,000 PRODUCTS - COMP/OP AGG \$ Excluded \$
A	AUTOMOBILE LIABILITY <input type="checkbox"/> ANY AUTO <input type="checkbox"/> OWNED AUTOS ONLY <input type="checkbox"/> SCHEDULED AUTOS <input checked="" type="checkbox"/> HIRED AUTOS ONLY <input checked="" type="checkbox"/> NON-OWNED AUTOS ONLY			BA3P574601	1/15/2022	1/15/2023	COMBINED SINGLE LIMIT (Ea accident) \$ 1,000,000 BODILY INJURY (Per person) \$ BODILY INJURY (Per accident) \$ PROPERTY DAMAGE (Per accident) \$ \$
B	<input checked="" type="checkbox"/> UMBRELLA LIAB <input checked="" type="checkbox"/> OCCUR <input type="checkbox"/> EXCESS LIAB <input type="checkbox"/> CLAIMS-MADE <input type="checkbox"/> DED <input checked="" type="checkbox"/> RETENTION \$ 10,000			CUP3P736065	1/15/2022	1/15/2023	EACH OCCURRENCE \$ 5,000,000 AGGREGATE \$ 5,000,000 \$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? <input type="checkbox"/> Y/N <input checked="" type="checkbox"/> N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						<input type="checkbox"/> PER STATUTE <input type="checkbox"/> OTHER E.L. EACH ACCIDENT \$ E.L. DISEASE - EA EMPLOYEE \$ E.L. DISEASE - POLICY LIMIT \$
B	Products Liability			ZPP21P37034	1/15/2022	1/15/2023	Per Occurrence \$10,000,000 Aggregate \$10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER**CANCELLATION**

For Informational Purposes Only

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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Request for Taxpayer Identification Number and Certification

Give Form to the
requester. Do not
send to the IRS.

▶ Go to www.irs.gov/FormW9 for instructions and the latest information.

Print or type.
See Specific Instructions on page 3.

1 Name (as shown on your income tax return). Name is required on this line; do not leave this line blank. Royal Biologics, Inc.	
2 Business name/disregarded entity name, if different from above	
3 Check appropriate box for federal tax classification of the person whose name is entered on line 1. Check only one of the following seven boxes.	
<input type="checkbox"/> Individual/sole proprietor or single-member LLC <input checked="" type="checkbox"/> C Corporation <input type="checkbox"/> S Corporation <input type="checkbox"/> Partnership <input type="checkbox"/> Trust/estate <input type="checkbox"/> Limited liability company. Enter the tax classification (C=C corporation, S=S corporation, P=Partnership) ▶ _____ <small>Note: Check the appropriate box in the line above for the tax classification of the single-member owner. Do not check LLC if the LLC is classified as a single-member LLC that is disregarded from the owner unless the owner of the LLC is another LLC that is not disregarded from the owner for U.S. federal tax purposes. Otherwise, a single-member LLC that is disregarded from the owner should check the appropriate box for the tax classification of its owner.</small> <input type="checkbox"/> Other (see instructions) ▶ _____	
4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3): Exempt payee code (if any) _____ Exemption from FATCA reporting code (if any) _____ <small>(Applies to accounts maintained outside the U.S.)</small>	
5 Address (number, street, and apt. or suite no.) See instructions. 401 Hackensack Ave Suite 604	Requester's name and address (optional)
6 City, state, and ZIP code Hackensack, NJ 07601	
7 List account number(s) here (optional)	

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. Also see *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number									
OR									
Employer identification number									
4	7		-	5	6	6	9	3	5

Part II Certification

Under penalties of perjury, I certify that:

- The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
- I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
- I am a U.S. citizen or other U.S. person (defined below); and
- The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here	Signature of U.S. person ▶	Date ▶ <u>12/5/19</u>
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General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to www.irs.gov/FormW9.

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS must obtain your correct taxpayer identification number (TIN) which may be your social security number (SSN), individual taxpayer identification number (ITIN), adoption taxpayer identification number (ATIN), or employer identification number (EIN), to report on an information return the amount paid to you, or other amount reportable on an information return. Examples of information returns include, but are not limited to, the following.

- Form 1099-INT (interest earned or paid)

- Form 1099-DIV (dividends, including those from stocks or mutual funds)
- Form 1099-MISC (various types of income, prizes, awards, or gross proceeds)
- Form 1099-B (stock or mutual fund sales and certain other transactions by brokers)
- Form 1099-S (proceeds from real estate transactions)
- Form 1099-K (merchant card and third party network transactions)
- Form 1098 (home mortgage interest), 1098-E (student loan interest), 1098-T (tuition)
- Form 1099-C (canceled debt)
- Form 1099-A (acquisition or abandonment of secured property)

Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN.

If you do not return Form W-9 to the requester with a TIN, you might be subject to backup withholding. See What is backup withholding, later.



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