Biolife, LLC
c/o Karen O'Toole
Manager, Quality Assurance and Regulatory Affairs
1235 Tallevast Road
Sarasota, Florida 34243-3271

June 11, 2023

Re: K070520
Trade/Device Name: PRO QR (Quick Relief)® Powder
Regulatory Class: Unclassified
Product Code: QSY

Dear Karen O'Toole:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 23, 2007 and correction letter dated November 6, 2007. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSY.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 6 2007

Biolife, L.L.C.
% Ms. Karen O'Toole
Manager, Quality Assurance
and Regulatory Affairs
1235 Tallevast Road
Sarasota, Florida 34243

Re: K070520
Trade/Device Name: PRO QR (Quick Relief)® Powder
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 14, 2007
Received: September 17, 2007

Dear Ms. O'Toole:

This letter corrects our substantially equivalent letter of October 23, 2007.

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K070530

Device Name: **PRO QR (Quick Relief)® Powder**

(for Minor External Bleeding From Wound & Procedures)

Indications for Use:

PRO QR Powder is intended for use to stop minor bleeding and to absorb body fluid in traumatic superficial lacerations or wounds. Once exudation and bleeding have stopped, a protective dressing can be applied. It is intended to be distributed as a Professional Use (Non-Prescription) Device.

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 CDRH, Office of Device Evaluation (ODE) Page __ of __

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070530

OCT 23 2007

K070520

1/3

SECTION 5: 510(k) SUMMARY

5.1 Sponsor

Biolife, LLC

1235 Tallevast Road

Sarasota, FL 34243

Telephone: 941-360-1300

Fax: 941-355-2187

Registration Number: 1066421

Contact Person: Karen O'Toole

5.2 Date Summary was Prepared

February 15, 2007

5.3 Device Information

Proprietary Name:	PRO QR (Quick Relief) ® Powder (for Minor External Bleeding From Wounds and Procedures)
Common Name:	Powder Wound Dressing
Classification Name:	Dressing, Unclassified

5.4 Predicate Device

Hemostace, LLC; Sorbastace (K965034)

5.5 Device Description

Components – The PRO QR product is composed of two main components: potassium iron oxyacid salt and a hydrophilic polymer.

Mechanism of Action – The PRO QR achieves its principle intended action (hemostasis) by creating a physical barrier or seal to the blood flow.

5.6 Intended Use

PRO QR Powder is intended for use to stop minor bleeding and to absorb body fluid in traumatic superficial lacerations or wounds. Once exudation and bleeding have stopped, a protective dressing can be applied. It is intended to be distributed as a Professional Use (Non-Prescription) Device.

5.7 Substantial Equivalence

PRO QR has identical claims to the Sorbastace (K965034) predicate, in that it is intended to be applied to traumatic, superficial lacerations or wounds to absorb body fluid and stop minor bleeding for Over the Counter (OTC) use. The subject and predicate device are made from materials which have demonstrated satisfactory biocompatibility, are highly absorbent for collecting body fluids, and are sterile, single use devices.

5.8 Performance Testing

Biocompatibility – Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Ames Mutagenicity

In vitro Testing – Absorption Study, Acid Base Interaction Study, Scanning Electron Microscopy (SEM) Analysis, Potassium (K) and Iron (Fe) Extraction

Animal Study – A swine model of lethal, arterial extremity injury

K070120

3/3

5.9 Conclusion

PRO QR Powder has the same intended use as the predicate device and differs only in the composition which has been shown to be biocompatible (based on the data in the submission) and raises no issue of safety or effectiveness. Both products arrest the flow of body fluids or blood by fluid dehydration (polymeric component) and protein coagulation or agglomeration (aluminum oxyacid salt versus potassium iron oxyacid salt).

Biolife, LLC believes that, as a result of the biocompatibility testing, *in vitro* testing, and the animal study, PRO QR is safe and effective for the control of bleeding wounds, absorption of body fluids and performs in a manner equivalent to the predicate.