Biolife, LLC
c/o Karen O'Toole
Manager, QA/RA
1235 Tallevast Road
Sarasota, Florida 34243-3271

July 28, 2023

Re: K080210
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 February 10, 2009. 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

FEB 10 2009

Biolife, LLC
% Ms. Karen O'Toole
Manager, QA/RA
1235 Tallevast Road
Sarasota, Florida 34243

Re: K080210
Trade/Device Name: PRO QR (Quick Relief)® Powder
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 12, 2009
Received: January 13, 2009

Dear Ms. O'Toole:

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.

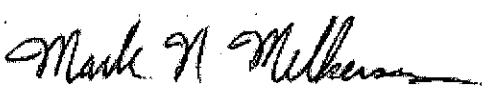
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

Device Name: PRO QR (Quick Relief)® Powder

Indications for Use:

OTC:
PRO QR Powder for minor external bleeding from wounds and procedures is intended for use as a topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures.

Rx:
PRO QR Powder for moderate to severe external bleeding wounds is intended for emergency use of temporary external treatment for controlling moderate to severe bleeding.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (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 1 of 1

Mark RPogle for mxm

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

510(k) Number K080210

SECTION 5: 510(k) SUMMARY

FEB 10 2009

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

January 12, 2009

5.3 Device Information

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

5.4 Predicate Device

Biolife, L.L.C.; PRO QR (Quick Relief)® Powder (K070520)

Medafor, Inc.; HemaDerm (K021678)

On Site Gas Systems, Inc.; QuikClot (K013390)

5.5 Device Description

Components – QR Powder is composed of two main components: potassium iron oxyacid salt, and a hydrophilic polymer.

Mechanism of Action – QR Powder achieves its principle intended action (hemostasis) by creating a physical barrier or seal to stop the flow of blood. When poured on a wound and upon contact with blood or exudate, in combination with manual pressure to the wound, QR Powder quickly forms a strong seal that completely covers the wound.

5.6 Intended Use

PRO QR Powder for minor external bleeding from wounds and procedures is intended for OTC use as a topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures.

PRO QR Powder for moderate to severe external bleeding wounds (Rx) is intended for emergency use of temporary external treatment for controlling moderate to severe bleeding.

5.7 Substantial Equivalence

PRO QR Powder has substantially equivalent indications to the HemaDerm (K021678) and QuikClot (K013390) predicates in that they are indicated for topical application as an aid in the control of temporary external bleeding associated with minor to severely bleeding wounds. PRO QR Powder (K080210) uses the same safe and effective technology as PRO QR (K070520). The subject and predicate devices 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 Testing–

Cytotoxicity, Sensitization, Irritation (skin and mucosal surface), Acute Systemic Toxicity, Ames Mutagenicity, Endotoxin, Pyrogen, Analysis of Hydrophilic Polymer for Styrene, Ethylstyrene and DVB, Histologic Assessment of Acute PRO QR Exposure in a Porcine Wound Model, IR Analysis of QR Powder and hydrophilic polymer for cellulose, XRD and XRF for potassium iron oxyacid salt impurities.

In vitro Testing – Absorption Study, Acid Base Interaction Study, Scanning Electron Microscopy (SEM) Analysis, Potassium (K) and Iron (Fe) Extraction, Gravimetric Determinations of PRO QR, Hemostatic Properties of PRO QR Powder as a function of its Quantitative Stability-Indicating Moisture and Potassium Iron Oxyacid Salt content.

Animal Studies

Animal Study 1 - A GLP Preclinical Study Evaluating Hemostasis Efficacy and Safety Using PRO QR Advanced Formula Powder in the Swine Model – QRPA Series

Animal Study 2 - Evaluation of a Novel Hemostatic Agent for Rapid Hemorrhage Control in a Model of Lethal Arterial Extremity Injury in Swine.

Animal Study 3 – A Swine Model to Demonstrate Powder Coverage Area and to Demonstrate That PRO QR Does Not Impede Healing

Clinical Study - Not Applicable.

5.9 Conclusion

PRO QR Powder induce hemostasis by fluid dehydration, protein coagulation and agglomeration the same as PRO QR (K070520) predicate device. QR Powder has been shown in testing to be equivalent to, if not better than, the QuikClot Powder predicate device in rapid hemorrhage control in a swine model of lethal arterial extremity. In addition study results for safety showed that QR Powder provided a significant advantage over QuikClot. Safety and efficacy was also demonstrated for bleeding control in vascular access procedures using a swine model both acutely and subchronically (2 weeks). Biolife, LLC believes that, as a result of the biocompatibility testing, *in vitro* testing, and non-clinical animal testing, PRO QR Powder is safe and effective as an aid in the control of temporary external bleeding associated with moderate to severe bleeding. PRO QR Powder is substantially equivalent to the predicate devices, PRO QR Powder, HemaDerm, and QuikClot.