AVIENT™
GLS Thermoplastic Elastomers

Avient Corporation
833 Ridgeview Drive
McHenry, IL 60050
United States
phone 815.385.8500
fax 815.385.8533
www.avient.com

Date: February 10, 2021

Charles Palacio
Andwin Scientific
167 W. Cochran St.
Simi Valley, CA 93065
cpalacio@andwin.com

RE: **USP Class VI, ISO 10993**

Dear Valued Customer,

This correspondence is in response to your request for information regarding the following Avient Corporation (formerly PolyOne Corporation) GLS Thermoplastic Elastomer products under USP Class VI and ISO 10993:

Product Name/Number
DYNAFLEX™ G2711-1000-00 /EM1001609610

Avient (GLS Corporation) received the following conclusions from an outside test laboratory on these products:

1) Meets the requirements of the guidelines for the Biological Test for Plastics, Class VI - 70°C.
    a. USP 25, NF 20, 2002. <88> Biological Reactivity Tests, *In Vivo*
2) Considered non-hemolytic
    a. ISO 10993-4, 2002 guidelines.
3) Considered non-cytotoxic and meets the requirements of the L929 MEM Elution Test
    a. ISO 10993-5, 1999 guidelines.

Although we are providing the information above, only actual testing of the final medical device product will positively establish this status for your final product. Please note that meeting Class VI criteria is only the base starting point. The ultimate suitability for use in a medical device application would depend on the specifics of the final product, its specific end use application and meeting the USP or ISO testing criteria required for that specific end use application.

Avient does not control the conditions under which our products are used in our customer's products. Therefore, we are not in a position to warrant that the customer's products meet FDA or other regulatory requirements.

Sincerely,

Digitally signed by Kristen Hardesty
DN: cn=Kristen Hardesty, o=PolyOne - GLS Thermoplastic Elastomers, ou=Product Stewardship, email=kristen.hardesty@polyone.com, c=US
Date: 2021.02.10 15:12:55 -06'00'

Kristen Hardesty
Regulatory Manager