



Scion Cardio-Vascular, Inc.
c/o Dennis Hammond
Director QA/RA
14256 SW 119th Ave.
Miami, Florida 33186

July 28, 2023

Re: K092552
Trade/Device Name: Clo-Sur^{PLUS} P.A.D.
Regulatory Class: Unclassified
Product Code: QSY, LYA

Dear Dennis Hammond:

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 September 4, 2009. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product codes QSY and LYA.

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
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