

Acknowledgment Letter

10/17/2017

Regina McIntosh, Executive Vice Pesident and General Manager Amsino International Inc 708 Corporate Center Drive Pomona, CA 91768 UNITED STATES

Dear Regina McIntosh:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K173178 Received: 10/2/2017 Applicant: Amsino International Inc Device: PUGGLE Enteral Pump Set

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to <u>http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm</u>.

Sincerely yours,

Center for Devices and Radiological Health