



HeartSine Distributor Tracking Requirements

Tracking Requirements



- What to report?
 - Serial number
 - Pad-Pak lot number
 - Customer supply date
 - Customer name (ship-to location)
 - Customer address (ship-to location)
 - Customer phone number (ship-to location)
 - Prescribing physician name and contact information, including phone number

Tracking Requirements (cont'd)



- When to report?
 - Within one month of sale by distributor
 - Due date: 5th business day of month for prior month's sales
- How to report?
 - Use provided HeartSine Excel template and send to tracking@heartsine.com OR
 - Submit own report as long as all required information is included OR
 - Enter via online tracking system (currently available to direct distributors only)

Non-Compliance & Escalation



- 6 weeks overdue from end of shipping month: Initial email request sent
- 2 weeks after first request: Formal warning letter sent
- 2 weeks after warning letter: Sales dept. informed and shipments suspended
 - Channels: Premier partner instructed to stop supply until tracking received
- 2 weeks after shipments are suspended the FDA is informed if no action has been noted from previous communications

New Online Tracking System



- New enhanced system allows direct distributors and channel partners to see serial numbers and Pad-Paks allocated to them so they can then enter the tracking information directly into the HeartSine tracking database
- Timing: Expected to go live before end of 2014