



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506

SEP 14 2010

Telephone: 949-608-2900

FAX: 949-608-4415

Dean S. Irwin
CEO
RA Medical Systems Inc
2270 Camino Vida Robel Suite L
Carlsbad, CA 92011

Dear Mr. Irwin:

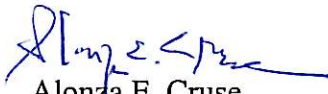
We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your premises at RA Medical Systems Inc., 2270 Camino Vida Robel Suite L, Carlsbad, CA on May 19 - 24, 2010 by Investigator Yvette E. Guillermo on behalf of the U.S. Food and Drug Administration (FDA). When the agency concludes that an inspection is closed under Title 21, Code of Federal Regulations, Section 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

The Agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it reflects only first party redaction's made by the Agency which protects any confidential information external to your firm. This, however, does not preclude you from requesting any additional information under the Freedom of Information Act (FOI).

If there are any questions about released information, feel free to contact me at (949) 608-2900 or write to:

U.S. Food and Drug Administration
ATTN: Compliance Branch
19701 Fairchild
Irvine, CA 92612-2506

Sincerely,


Alonza E. Cruse
District Director

Enclosure