Annual Report Review Complete

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The Food and Drug Administration (FDA) has reviewed the Annual Report to your Investigational Device Exemption (IDE) Application and has determined that you have met the requirements of 21 CFR 812.150(b)(4) and (5). No further information is required at this time. Future updates to investigator and IRB information may be submitted annually as part of your IDE progress report in lieu of 6-month investigator reports. This notification is being sent in lieu of a formal written letter. If you have any questions, please contact Paula Caposino at 301-796-6160 or Paula.Caposino@fda.hhs.gov.

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