



VIA E-MAIL

Accuitis, Inc.  
Attention: Rick Coulon  
307 Mary Street  
Clarksville, Georgia 30523

Re: Submission of Clinical Trial Information Pursuant to 42 U.S.C. 282(j)  
FDA Reference Number: CDER-2021-105  
NCT 03064438

Dear Mr. Coulon:

On July 27, 2021, the Food and Drug Administration (FDA) sent your company a Notice of Noncompliance, dated July 26, 2021, regarding the requirements to submit clinical trial information to the ClinicalTrials.gov data bank. At this time, it appears that your company has addressed the issues raised in FDA's letter.

Sincerely,

*{See appended electronic signature page}*

Laurie Muldowney, M.D.  
Deputy Director  
Office of Scientific Investigations  
Office of Compliance  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration

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/s/  
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LAURIE B MULDOWNEY  
05/26/2022 01:48:04 PM