

Vision Pro Master File Checklist

Thank you for your interest in the Apple Vision Pro FDA Master File (MAF). Before submitting your application, please ensure you have reviewed the information below and completed all required steps.

A signed Letter of Authorization (LOA) from Apple is required to use the Apple Vision Pro MAF as part of your FDA premarket submission. This application requests information for Apple to determine your eligibility to receive an LOA.

In order to reference the Apple Vision Pro MAF on file with the FDA you must confirm you are submitting a premarket submission to the FDA for a software medical device on Apple Vision Pro and have an Apple Developer Team ID (create an [Apple Developer account](#) if you don't already have one). [Apple Developer](#) accounts provide the tools, resources, and support you need to develop and distribute apps, including access to app services, testing tools, app analytics, etc.

If granted, Apple will use the information in this application to prepare and issue an LOA to you. The LOA should be included as part of your premarket submission to the FDA. The LOA provides permission to the FDA to reference the content contained within the Apple Vision Pro MAF while reviewing your submission.

To apply for an Apple Vision Pro MAF LOA, make sure:

- 1. You are building a software medical device for use on Apple Vision Pro that requires FDA premarket review and authorization.**
- 2. You have an Apple Developer Team ID.**
- 3. You have completed the MAF LOA Application Form.**
 - Answer all questions thoroughly and accurately to prevent delays.
 - Ensure the information in the form is consistent with your Apple Developer Team ID and FDA submission.
 - Email the form to mafrequest@apple.com
- 4. Next Steps After Application:**
 - If your application is granted, you will be emailed a signed LOA to the email address specified in the application form. The LOA must be included in your submission to the FDA in order for the content in the MAF to be considered as part of your FDA premarket submission.

Apple Vision Pro Master File Application

Please send your completed form to mafrequest@apple.com
Attach additional pages as necessary.



1. Entity / Individual:

Contact Name

Contact Email

Apple Developer Team ID

FDA Submission Entity / Individual Name

FDA Submission Entity / Individual Mailing Address

Are you submitting a premarket submission to the FDA for a software medical device on Apple Vision Pro?

☐ Yes ☐ No

2. Medical Device:

Trade Name of your Medical Device

What is the trade name of the medical device you will be submitting to the FDA?