

## FDA Establishment Registration & Device Listing – Information

### Step 1: Device Classification and Exemption Confirmation

Field	Fill In
Device Common Name	STRABO Glasses
Product Code	HOY
Regulation Number	886.4750
Device Class	1
510(k) Exempt? (Yes/No)	Yes
Reason for Exemption	<p>Under 21 CFR 886.4750, the ophthalmic eye shield (Product Code HOY) is classified as a Class I device and is exempt from the premarket notification [510(k)] requirements, unless it is intended for a use different from the legally marketed device or operates using a different fundamental scientific technology.</p> <p>This exemption applies because:</p> <p>Low Risk: The device poses minimal potential harm to the user.</p> <p>General Controls Sufficient: The FDA has determined that general controls (e.g., establishment registration, device listing, good manufacturing practices, labeling, etc.) are adequate to assure the safety and effectiveness of the device.</p> <p>Not a Novel Use: STRABO Glasses are presumed to perform the same function as existing, legally marketed eye shields.</p>
Link to FDA Classification	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=HOY">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=HOY</a>

### Step 2: Establishment Information – Manufacturer (China)

Field	Fill In
Company Name	Shenzhen Calison Technology Co., limited
Business Address	B711, Yesun technology Building, Guanlan street, Longhua district

City, State/Province	Shenzhen city, Guangdong province
Country	China
Postal Code	518110
Phone	+86 18825281935
Contact Person	Kay Zhao
Contact Email	<a href="mailto:kay@calison3d.com">kay@calison3d.com</a>
DUNS Number	<b>701443344</b>
Role in Supply Chain	Manufacturer
US Agent Name	Clear Vision Strabo LLC
US Agent Email	<a href="mailto:tjr@cvt-ai.com">tjr@cvt-ai.com</a>

### Step 3: Establishment Information – Specification Developer (Armenia)

Field	Fill In
Company Name	Vision Lab Co, LLC
Business Address	32 Komitas Avenue, apartment 42
City, State/Province	Yerevan
Country	Armenia
Postal Code	0051
Phone	+374 77 934700
Contact Person	Onik Aznauryan
Contact Email	<a href="mailto:onik@prozrenie.ru">onik@prozrenie.ru</a>
DUNS Number	933896253
Role in Supply Chain	Specification Developer/Product Owner
US Agent Name	Clear Vision Strabo LLC
US Agent Email	<a href="mailto:tjr@cvt-ai.com">tjr@cvt-ai.com</a>

### Step 4: U.S. Agent (Clear Vision Strabo LLC)

Field	Fill In
Company Name	Clear Vision Strabo LLC
Business Address	850 New Burton Road, Suite 201, DE 19904
State	Delaware
Phone	614-312-3366
Contact Person	Tracy Robertson
Contact Email	<a href="mailto:tjr@cvt-ai.com">tjr@cvt-ai.com</a>
FDA FURLS Account ID	
Will serve as US Agent for (list firms)	

### Step 5: FDA User Fee Payment Info

#### Vision Lab

Field	Fill In
Payment Made For (Firm Name)	Vision Lab Co, LLC
Date of Payment	6/13/2025
Payment Identification Number (PIN)	50466187

Payment Confirmation Number (PCN)	25648202
Payment Method (Card/ACH/Wire)	

### Calison

Field	Fill In
Payment Made For (Firm Name)	Shenzhen Calison Technology Co., limited
Date of Payment	6/18/2025
Payment Identification Number (PIN)	50466237
Payment Confirmation Number (PCN)	25648256
Payment Method (Card/ACH/Wire)	

### Step 6: Device Listing Information

Field	Fill In
Proprietary Name of Device	STRABO Glasses
Common Name	Ophthalmic Eye Shield
Product Code	HOY
Regulation Number	886.4750
Device Class	I
Is it 510(k) Exempt?	Yes
Manufacturer	
Specification Developer	
Labeling Document File Name	
Intended Use / Indications	STRABO glasses are intended for therapeutic orthoptic and pleoptic exercises to treat amblyopia and strabismus. They aim to improve visual acuity, eliminate functional scotomas, and enhance binocular vision through precise electronic occlusion therapy.
Sterile? (Yes/No)	No
Software Involved? (Yes/No)	
Uploads: IFU, Labels (PDF)	

### Step 7: Annual Renewal Checklist (for future use)

Field	Fill In
Year	
Renewal Window (Oct 1 – Dec 31)?	
Payment Submitted?	Yes/No
Fee Paid	\$

Listing Verified and Updated?	Yes/No
Changes to Establishment Info?	Yes/No
Changes to Device Info?	Yes/No
Notes	