UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

DIVISION OF
CORPORATION FINANCE

December 10, 2024

Patrick Schnegelsberg
Chief Executive Officer
Picard Medical, Inc.
4 Palo Alto Square, Suite 200
Palo Alto, CA 94025

Re: Picard Medical, Inc.
Amendment No. 1 to Draft Registration Statement on Form S-1
Submitted November 12, 2024
CIK No. 0002030617

Dear Patrick Schnegelsberg:

We have reviewed your amended draft registration statement and have the following comments.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe a comment applies to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to this letter and your amended draft registration statement or filed registration statement, we may have additional comments.

Amendment No. 1 to Draft Registration Statement on Form S-1

Prospectus Summary, page 1

1. We note your disclosure on page 1 that "SynCardia was incorporated in Delaware in August 2001 as SynCardia Systems, Inc." and your disclosure on page 3 noting that "[t]he 70cc SynCardia TAH is designed for implantation into adult patients and has supported over 1,939 patients globally since 1982." Please revise your disclosure here and in your description of business to clarify the timeline of your operations, including the manufacturing and distribution of your products.
2. We note your disclosures here and in your description of business that you manufacture and sell "the only U.S. FDA, and Health Canada approved implantable SynCardia TAH," "the SynCardia TAH is an established alternative to heart

transplantation for patients with biventricular failure in the U.S., and around the world," and "[a] total artificial heart . . . does replace the heart." Please revise your disclosure here and throughout the filing, including your business description, to clarify that your product is approved in the United States and Canada for temporary bridge to transplantation indication, and briefly explain this type of approval as compared to approval for a long-term indication. Where you discuss that your product is an established alternative to heart transplantation, please clarify that your product is indicated for short-term support, and revise your disclosure to define Bridge to Transplantation and Bridge to Decision.

3. Please revise your prospectus summary to disclose that you have incurred net losses since inception and, as you disclose on page 59, that you expect to incur significant expenses and operating losses for the foreseeable future. Quantify your net losses and accumulated deficit for the financial periods presented in the filing.

4. We note your disclosure on page 4 that "[a]fter the introduction of the Freedom Driver, there have been documented accounts of patients playing golf and basketball, fishing, and hiking while on the SynCardia TAH." Please revise your disclosure to provide support for this statement, including the entity or person that observed and documented these accounts, the specific implanted device, the patients' health status prior to the implantation, the number of patients that were observed experiencing these outcomes, and any adverse events that occurred.

5. We note your disclosure that your products are "superior to peers in total artificial heart category" and your discussion of your competitors products, regulatory approvals, and clinical trials. We also note your disclosure describing the limitations of LVADs compared to your TAH. To the extent that head-to-head trials have not been conducted, please revise to remove comparisons of your product's performance or efficacy to other approved products.

6. Please revise your prospectus summary to disclose, as you do on page 59, that management has concluded that there is substantial doubt over your ability to continue as a going concern, and revise your risk factors to discuss the related risks to investors.

7. We note your disclosure on page 12 that, while you were working on the re-certification of the SynCardia TAH under MDD, BSI highlighted several post-market surveillance deficiencies and in May 2022, BSI suspended SynCardia's CE mark pending completion of a post-market surveillance study needed to reinstate the CE mark under MDD. We also note your disclosure on page 36 that your managers have identified significant issues with your regulatory compliance regime and are actively working to solve these issues. Please revise your disclosure here and in your relevant risk factor to discuss the specific post-market surveillance deficiencies and issues with your regulatory compliance regime, and clarify how you intend to address those deficiencies and issues, including your intended timeline for the same.

Risk Factors, page 19

8. We note your disclosure that in the event of a sale of shares in a public offering resulting in gross proceeds of $25 million to the Company, the conversion of your Series A-1 Preferred Stock will become mandatory. We also note your disclosure that,

in the event of an initial public offering, your related party loan would be automatically converted into common stock. Please revise to include a risk factor discussing the risks to investors related to these conversions, including those related to dilution and volatility.

SynCardia has significant customer concentrations . . ., page 23

9. We note your disclosure that a small number of your customers account for a substantial portion of your revenues. Please disclose, as you do in the notes to your financial statements, the customers that account for more than 10% of your revenue for the periods presented in the filing, and quantify the percentage contribution of each customer.

Use of Proceeds, page 48

10. We note your disclosure that a portion of your proceeds will be used to fund research and development activities of your products, and your disclosure elsewhere that you plan to conduct "first-in-animal trials" and clinical trials related to your products. Please identify any specific trials you intend to fund with proceeds from the offering and quantify the relevant amount of proceeds, as appropriate. In addition, please disclose the portion of proceeds you intend to use for each of the listed products.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations, page 55

11. In addition to quantifying your U.S. and non U.S. declines in revenues, expand your disclosures to address the specific underlying reason(s) for the $1.2 million decrease in revenues for the three months ended June 30, 2024 and the $.6 million decrease in revenues for the six months ended June 30, 2024.
12. Please expand your disclosures to discuss your cost of revenues as a percentage of revenues for each period presented. Address why you have negative gross margins for your rental revenues.
13. Expand your discussion of the change in cost of revenues to quantify the additional inventory reserves and other significant underlying reasons for the decrease in cost of sales in the three and six months ended June 30, 2024. Specifically address the reasons underlying the changes in your inventory reserves. Address this comment as it relates to your fiscal year cost of revenues discussions.
14. We note the significance of your research and development expenses. Please expand your disclosure to provide more detail for your research and development expenses for each period presented, including but not limited to by product candidate as well as by the nature of the expenses. To the extent that you do not track expenses by product candidate, please disclose as such.

Liquidity
Sources of Liquidity, page 60

15. We note your disclosure that "[t]o date, we have funded its operations primarily with the proceeds from Series A-1 Preferred Stock and loans from related parties." Please revise your disclosure in this section to discuss the material terms of the loans and

Series A-1 Preferred Stock issuances, including relevant dates, parties, interest rates, accrued or undeclared dividends, outstanding amounts, and any other material terms. Discuss the impact of these loans, share issuances, undeclared dividends, and related obligations on your liquidity.

Critical Accounting Policies, page 61

16. The disclosures of your critical accounting policies and estimates appear to be more descriptive of the accounting policies utilized, rather than any specific uncertainties underlying your estimates. Please revise the disclosures for each of your critical estimates made in preparing your consolidated financial statements to sufficiently explain to investors what each critical estimate is; the uncertainties associated with the critical estimates; the methods and assumptions used to make the critical estimates, including an explanation as to how you arrived at the assumptions used; the events or transactions that could materially impact the assumptions made; and how reasonably likely changes to those assumptions could impact your consolidated financial statements. Provide investors with quantified information to the extent meaningful and available. Refer to Item 303(b)(3) of Regulation S-K, Instruction 3 to Item (303)(b)(3), and Section V of Release No. 33-8350 for guidance.

Business
Our Components, page 67

17. Please address the following comments related to your components.

- We note your disclosure that, on April 11, 2022, "Heitek Automation and we entered into a purchase order, which covers the terms for purchasing the pneumatic manifold drawings for the C2 Driver." Please briefly describe the terms of this agreement, if material, and the significance to your business of purchasing these drawings.

- We note your disclosure that "we have started development of the C3 Driver, which is not expected to need this pneumatic manifold." Please revise to provide additional detail regarding the significance of the development of this driver to your product and your business, including the timing for the development of this driver and the significance to the manufacturing of your product.

Clinical Efficacy, page 69

18. We note your reference on page 66 to "the Freedom Driver System IDE Study that began in 2010," your reference on page 69 to "more recent studies examining the clinical outcomes of patients reviewing SynCardia TAH as BTT therapy," and your bulleted list of examples of a study, retrospective analysis, and prospective institutional database. Please revise your disclosure to clearly identify the studies, retrospective analysis and prospective institutional database. Clarify what is meant by an "all comer" patients, and disclose the criteria for selecting patients for the SynCardia TAH study between January 2014 and May 2019. Revise your disclosures to provide all material information about each study, including the sponsor of the study, number of participants, whether statistical significance was demonstrated, and

the p-values supporting statistical significance. The first time you use the term p-value please explain what it measures and the p-value that you have to achieve in order to conclude a statistically significant result.

Adverse Events, Including Those That Affected Outcomes. . ., page 70

19. Please revise your disclosure to provide a more detailed explanation of the data presented within the Adverse Events table on page 70, including the specific studies and devices related to the data presented, and whether and to what extent the events reported in the table were Serious Adverse Events. For events in the table that are scientific or technical terms, please clarify the meaning of these terms in order to ensure that lay readers will understand the disclosure. In addition, please provide further detail regarding the differences noted within the footnotes, including the circumstances under which patients ineligible to receive the implant per protocol received and implant, clarify the relationship between the N-values and the figures presented, clearly label the two columns under "All Events," and clarify whether the figures within all of the parentheticals represent percentages, as you indicate next to "number of patients (percent)."

Our Pipeline, page 70

20. We note your disclosure that "[t]he exchange of information and data prior to submission helps to align both parties and speeds up the approval timeline." Here and throughout your filing where you discuss regulatory approvals, please disclose that there is no guarantee you will receive regulatory approval, the timing is unknown, and approval may take longer than planned. Make conforming changes throughout your filing, including here and in your prospectus summary where you discuss the intended timing for FDA approval of your products and indications.

New Product Development, page 71

21. We note your disclosure that "[t]hese prototypes have been shown to achieve pulsatile flow with life-sustaining rates of cardiac output." Given that efficacy determinations are solely within the authority of the U.S. Food and Drug Administration, please revise this and all similar statements throughout your disclosure to remove such implications. We do not object to the disclosure of objective data obtained in your clinical studies.

Industry Overview, page 72

22. We note your disclosure that the total addressable market in the United States for the BTT indication is approximately $1 billion and the total addressable market in the United States for long-term indication is approximately $50 billion, based on 6,000 heart implants and approximately 300,000 patients, respectively. Please revise your disclosure to clarify how you arrived at the $1 billion TAM for BTT indication based on 6,000 patients, including how you determined that the market includes 6,000 patients and how you calculated these 6,000 patients represent a market opportunity of $1 billion. In addition, please clarify how you determined that the market for long-term indication included 300,000 patients and how you calculated a total market of $50 billion based upon these patients. In your discussion, clarify why your TAM

includes long-term indication given that you have yet to receive regulatory approval for this indication. As a related matter, where you discuss your serviceable addressable market, please provide more detail regarding how you arrived at an estimate of 1,400 implants in the United States, and how you calculated the $230 million SAM based on these heart implants. Please also clarify whether your SAM includes your BTT indication and/or long-term indication.

23. Where you provide statistics and data about your industry, please provide support for these statements or characterize the same as management's opinions or beliefs. If these disclosures are the opinions or beliefs of management, please provide the basis for their opinions or beliefs. In addition, where you refer to studies generally for support, please identify the studies.

Government Regulation, page 78

24. We note your disclosure that "stockholders are required to perform their own analysis of regulations that apply to our business." Given that Item 101 of Regulation S-K requires disclosure of the material effect that compliance with government regulations may have on your business, and because investors are entitled to rely upon your disclosure within the registration statement, please revise your disclosure to remove this qualification.

25. We note your references throughout your filing to Humanitarian Device Exemption as a pathway for commercialization of your products. Please revise this section to discuss the regulations related to HDE approval.

Management, page 83

26. We note your disclosures that you have wholly owned German and Australian subsidiaries and that, pursuant to your Investment Agreement, you intend to purchase a majority interest in SynCardia Medical (Beijing), Inc. Please tell us whether any of your executive officers and directors reside outside of the United States and revise your disclosure accordingly. To the extent applicable, please also include disclosure describing any limitations on service of process and enforcement of civil liabilities for any directors or officers residing outside of the United States.

Principal Stockholders, page 95

27. Please disclose the natural person(s) with voting and dispositive control of the shares held by Hunniwell Picard I.

Description of Capital Stock, page 96

28. Please revise your disclosure to include a description of your outstanding Series A-1 Preferred Shares, including voting rights, conversion rights, and dividend rights.

Audited Financial Statements
Note 7. Commitments and Contingencies
(c) China Corporation, page F-19

29. We note your disclosure that contingent on the Company becoming publicly traded on a stock exchange, it would be committed to contribute approximately $2.85 million in

exchange for a 60% ownership interest in SynCardia Beijing. Based on this commitment, it would appear that the acquisition of SynCardia Beijing is probable. As such, please provide us with your significant subsidiary tests and address the need to provide the financial statements of SynCardia Beijing and related pro forma financial information. Refer to Rule 8-04 and 8-05 of Regulation S-X.

Note 9. Temporary Equity and Stockholder's Deficit
(a) Redeemable Convertible Preferred Stock, page F-20

30. We have the following comments regarding your redeemable convertible preferred stock:

- Disclose the nature of the redemption features such that they are outside the control of the Company.

- For each issuance discussed, disclose the conversion price and the redemption price per share.

- We note that in December 2022, 791,857 shares of Series A-1 Preferred Stock were sold for cash proceeds at a price of $3.35 per share, and 5,550,000 shares of Series A-1 Preferred Stock were issued for payment in kind of notes payable at a price of $1.00 per share. With reference to the 5,550,000 shares issued for payment of notes payable at $1.00 and the original terms of the notes payable, please tell us what consideration was given to recognizing a loss on the extinguishment of the notes payable based on the apparent $3.35 fair value of the preferred stock issued.

Interim Financial Statements
Note 8. Convertible Notes, page F-48

31. We note that in July 2024, the conversion price of the 2024 Convertible Notes was modified to reduce the conversion percentage from 80% of the lowest price per share paid by the other purchasers of equity securities in the IPO to 50%. Please ensure your updated interim financial statements discuss any accounting implications related to this change in terms and provide us with the specific authoritative literature you relied on. Also, clarify whether the conversion terms of the 2023 Convertible Notes were modified.

Note. 15 Subsequent Events
Related Party Transactions, page F-53

32. We note that effective July 2, 2024, all loans outstanding as of June 20, 2024, from Richard Fang, Fang Family Fund, LLC and Fang Family Fund II, LLC, were consolidated into one loan with a total principal amount of $7,046,090. This loan accrues simple interest at the rate of 6% per annum, and is repayable after six months, unless amended. However, in the event of an initial public offering, while the loan remains outstanding, all principal, together with all unpaid accrued interest, would be automatically converted into common stock of the Company at a 50% discount to the

lowest price per share paid by the other purchasers of the equity securities in the initial public offering. With reference to the original terms of these loans and the apparent new conversion terms, please ensure your updated financial statements address any accounting implications of the conversion terms, including the need to recognize an inducement expense upon the conversion. Refer to the appropriate authoritative literature.

Exhibits

33. Please file all material agreements, including but not limited to the Investment Agreement with SynCardia Medical (Beijing), Inc., the lease for your Tucson facility, and your equity incentive plans, as exhibits to the registration statement, or provide an analysis as to why you believe they are not required. See Item 601 of Regulation S-K.

General

34. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications. Please contact the staff member associated with the review of this filing to discuss how to submit the materials, if any, to us for our review.

Please contact Julie Sherman at 202-551-3640 or Jeanne Baker at 202-551-3691 if you have questions regarding comments on the financial statements and related matters. Please contact Benjamin Richie at 202-551-7857 or Katherine Bagley at 202-551-2545 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Industrial Applications and Services

cc: Michael J. Blankenship