Draft of Responses to Queries Put by Charles B. Brown, Special Assistant for Patent Policy, Department of Health, Education, and Welfare, to Dr. Adrian Kantrowitz in letter of June 30, 1967

Question 1: Who constructed the first prototype of the ventricle described in the AVCO application and the 1963 article? When was it constructed?

The "Silastic bulb* with woven Teflon cuffs" described under Design of the Prosthesis in the 1963 article from this laboratory and used in experiments on 28 mongrel dogs was designed and fabricated in the Maimonides laboratory by Dr. Nose in June of 1962, (exact date to be determined). Several of these "inner bladders" are preserved in the laboratory and are available, as is an unpublished photograph of one of these bladders. Experimental records of use of these Silastic bulbs with decreasing diameters and open ends (which are referred to as "Neimeth" in Dr. Nose's reports) are also available.

Findings and experiences with these Silastic bulbs were communicated to Avco in frequent visits, conversations, and correspondence, and the suggestions and recommendations were incorporated in the "Lucite-encased Silastic bulb" referred to under Materials and Methods, which was constructed by Avco. This was the first prototype of the ventricle described in the Avco application. Our experimental records indicate that the implantable 2-layer Avco prosthesis was first used in an experiment on a dog at Maimonides Hospital on August 15, 1962. It should also be noted that Dow Corning, Midland,

Michigan, provided a number of 2-layer booster hearts, the first of which was used in an animal experiment on July 27, 1962 (to be confirmed).

Question 2: Who constructed the specific ventricle shown in the photograph in Fig. 4 of your 1963 article?

The auxiliary ventricle shown in Fig. 4 of the 1963 article was constructed by the Avco Company, incorporating specifications provided by Drs. Nose and Kantrowitz, as outlined in the answers to Questions 5 and 6. The unit shown in Figure 4 was used, as nearly as we can establish, in an experiment performed on_____. We do not know the date of its fabrication.

Question 3: Do you consider that either you or your staff suggested or made suggestions that led to the ellipsoidal shape of the ventricle or the decreasing throat diameter feature?

I consider that the contributions and suggestions of my staff and I were integral in the evolution of the two-layered ellipsoidal booster heart. Specifications and suggestions for the design of this unit were given to the Avco Company by the Maimonides group, and throughout the development of the unit portrayed in Fig. 4 of our 1963 article there was constant discussion of the unit and exchange of information and suggestions between the two groups.

<u>Question 4</u>: Did your laboratory prepare the drawings shown in Figures 1, 2, and 3 of your 1963 article? If so, were copies given to Avco? Please give details, including dates.

Figures 1, 2 and 3 of the 1963 article were prepared under the direction of the Surgical Research Laboratory personnel at Maimonides from drawings provided by Avco, which, in turn, were based on earlier suggestions by Dr. Nose. According to Dr. Nose's recollection, copies were sent to Avco. However, copies of correspondence are not available.

Question 5: Did you or your staff furnish Avco any engineering specifications relating to the design of the ellipsoidal shape ventricle?

The following are among the specifications and suggestions relating to the design of the ellipsoidal-shape ventricle that were furnished to Avco by personnel of the Maimonides Surgical Research Department:

1. The use of synthetic arterial grafts
2. The use of Silastic 382 and later, Silastic 372
3. The ellipsoidal shape
4. The use of a steel ring to enclose the ends of the outer casing (provided originally to Maimonides personnel by Dr. Hufnagel)
5. The design of the connection between the Dacron graft and the inner chamber
6. The pumping volumes of the prosthesis
7. The need for a rigid external casing

Examination of our records and questioning of former staff members of the Surgical Research Department may disclose still other specifications or suggestions given by us to Avco.

Question 6: Please advise us of any other factual details and furnish copies of other documentation which you feel may be of value in establishing your claim of inventorship to the invention claimed in the Avco patent application.

We believe that the following chronology of events leading to the development of the "Lucite-encased Silastic bulb" described in our 1963 article, determined as exactly as we can, is typical of the information that can be derived from our records.

April 18, 1962: Dr. Nose joined the staff of the Surgical Research Department of Maimonides.

May 4-5, 1962: Dr. Nose, Dr. Adrian Kantrowitz, Dr. Martin Schamaun, Dr. Nonoyama, and Dr. Saltiel went to Boston to discuss a joint effort to develop an auxiliary ventricle with Avco representatives. Dr. Nose discussed materials problems. Dr. Kantrowitz discussed the cardiac and diastolic augmentation physiology. Dr. Nonoyama discussed the timing circuit.

May 9, 1962: Dr. Nose went to Boston to give Avco representatives further explanation of the booster heart; he was joined a day later by Dr. Adrian Kantrowitz. Drs. Nose and Kantrowitz specified the material to be used in constructing the booster heart (Silastic 382 for the inner bulb, synthetic arterial graft for the limbs of the unit), and the manner in which the inner chamber and the graft were to be connected. Drs. Nose and Kantrowitz brought the synthetic arterial graft to Avco, and Dow-Corning Silastic materials were procured by the Surgical Research Laboratory of Maimonides Hospital and furnished to Avco.

May 1962, exact dates to be determined: Dr. Nose made prototype booster hearts (consisting of the internal bladder only) and tested them experimentally. Dr. Nose determined from these studies that an ellipsoidal contour of the booster heart was desirable, and he presented this recommendation to Avco personnel, as well as various suggestions regarding materials, details of construction, implantation technique, and the like. In other studies, Dr. Nose tested various locations of the booster heart and determined that implantation in the aortic arch bypass position yielded the most desirable hemodynamic results.

May 25, 1962: At a meeting in Boston, Mr. Fred Russell of Avco showed an apparatus which had been constructed in an effort to embody the foregoing suggestions of Drs. Nose and Kantrowitz in a simulation system.

June 14, 1962: Mr. Fred Russell came to Maimonides Hospital with a bladder fabricated by Avco to observe an animal experiment. This unit failed.

June 19, 1962: Dr. Nose performed an animal experiment, probably the first with a unit fabricated in the Maimonides Surgical Research Department. Dr. Nose's notes pertaining to this experiment include detailed instructions for the fabrication of the inner bladder and a method for connecting the Nylon or Dacron graft to the Silastic bladder involving the fraying of the ends of the graft. The ellipsoidal shape of the unit is portrayed in Dr. Nose's drawings.